

APPENDIX 2C-5

July 2005 Consolidated Pre-Meeting Comments

Peer Review of Proposed Human Health and Other Relevant Indicators for EPA's 2006 Report on the Environment

July 19, 2005

Notice:

Pre-meeting comments were prepared by each consultant individually prior to the meeting. They are preliminary comments only, and are used to help consultants become familiar with the document and charge questions, develop the agenda, and identify key issues for discussion. During the meeting, consultants may expand on or change opinions expressed in their pre-meeting remarks and may introduce additional issues. For these reasons, pre-meeting comments should be regarded as preliminary and do not reflect the final conclusions and recommendations of individual consultants. These pre-meeting comments will be included as an appendix in the meeting summary report, along with other background materials.

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Health Reviewer Biographies

Lynn Goldman, M.D., MPH

Johns Hopkins University
Bloomberg School of Public Health

The Honorable Lynn R. Goldman, a pediatrician and an epidemiologist, is a Professor in the Department of Environmental Health Sciences at the Johns Hopkins University Bloomberg School of Public Health, where her areas of focus are children's environmental health, public health practice, and chemical and pesticide regulatory policy. As Assistant Administrator for Toxic Substances at the U.S. Environmental Protection Agency, she directed the Office of Prevention, Pesticides and Toxic Substances (OPPTS) from 1993 through 1998. Prior to joining the EPA, Dr. Goldman served as head of the Division of Environmental and Occupational Disease Control of the California Department of Health Services. She has a BS in Conservation of Natural Resources from the University of California, Berkeley, an MPH from the Johns Hopkins University School of Public Health, and an MD from the University of California, San Francisco. She completed pediatric training at Children's Hospital, Oakland, California and is board certified in pediatrics.

James Listorti

James A. Listorti & Associates

Dr. Listorti holds a doctorate in public health in environmental quality management from Columbia University. He has worked for over 20 years at the World Bank dealing with environmental and health problems in developing countries, ranging from water, sanitation, housing, human settlements, transportation, energy, pollution management, malaria control, emergency preparedness, gender issues, environment, and climate change.

P. Barry Ryan

Emory University
Rollins School of Public Health

Dr. P. Barry Ryan has been active in the exposure assessment field for over 20 years. He has published in excess of 75 peer-reviewed manuscripts and made over 150 presentations of his work to the scientific community. His work has included both cross-sectional and longitudinal studies of community-based exposure for multiple pollutants in multiple media. Dr. Ryan is currently Principal Investigator on an EPA-funded STAR Grant designed to assess the effectiveness of biological markers of exposure to organophosphate and pyrethroid pesticides. He was Principal Investigator on the EPA funded longitudinal study of exposures to pollutants known as the National Human Exposure Assessment (NHEXAS) - Maryland study, and is Co-Principal Investigator of a study on health compromised individuals assessing the impact of particulate matter exposure on heart rate variability, and Co-Principal Investigator on a study of the impact of air pollution exposure on hiker lung-health in the Great Smoky Mountain National Park. In addition to these current investigations, Dr. Ryan has been Principal Investigator on studies of lead exposure experienced by adolescents in the greater Boston area. Dr. Ryan currently serves on the

Federal Advisory Committee for the National Children's Study. Recently, he was an *ad hoc* member of the FIFRA SAP on CCA-Treated Wood Products and the FIFRA SAP on Carbamate Pesticides. Dr. Ryan is a trained chemist and has a large laboratory facility. His wesbsite is <http://www.sph.emory.edu/eoh/faculty/ryan.html>

Bailus Walker

Howard University
College of Medicine

Bailus Walker, Jr, PhD, MPH: Professor of environmental and occupational health, College of Medicine, Howard University; PhD in epidemiology and toxicology, University of Minnesota; MPH (Environmental Health) University of Michigan. Research areas: Risk assessment/Risk Management; Mechanism of environmentally-induced diseases; health effect of lead on the intellectual capacity of inner-city children. More than 50 peer-reviewed scientific publications, most recent publications (2000-2004) in Journal of Inhalation Toxicology, Journal of Clinical and Laboratory Medicine, and Journal of Epidemiology and Toxicology.

Former Director, occupational health standards division, OSHA. Immediated past chairman, Committee on Toxicology, National Academy of Sciences. Chair, Risk Assessment Group, Board on Environmental Studies and Toxicology; Member, Committee to Review EPA's Research Program (2001-2003); Committee on Arsenic in Drinking Water, all of the National Academy of Sciences; Chairman, Board of Scientific Counselors, ATSDR, CDC; Chairman, Environmental Health Advisory Committee, NIH; Member, Review Group (Peer Review of Indicators), for EPA's Report on the Environment 2003.

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Comments for Group 1 Indicators

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Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **Life Expectancy**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (4)

Listorti: (4) Life expectancy at birth is a valid indicator for overall trends, but it includes too many variables that are not related to environmental conditions.

Ryan: (4) *Life Expectancy at Birth is an excellent indicator of overall health. It is hard to imagine an indicator that integrates over all causes of death better than this one. It is not, however, specific to any environmental insult, but rather includes genetic problems, accidents, etc. If the focus is to be on environmental issues, a more precise estimate that eliminates, for example, accidental deaths, homicides, and suicides, might be a better choice.*

Walker: (3) Life expectancy is a composite indicator. It reflects changes in the crude death rate, age adjusted mortality, changes in infant mortality and changes in childhood mortality and in childhood diseases as well as in disease that afflict adults. Therefore, it is useful as a proxy for health, and in evaluating human health and for contributing to the overall picture of health.

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (4)

Listorti: (2) It is minor importance to determine environmental causalities because of the number of possible variables, such as behavioral factors (e.g., exercise), overall nutrition (e.g., obesity), etc. But it should be kept as an indicator.

Ryan: (4) *The specific question to be addressed by the Group 1 indicators is “What are the trends in health status in the US?” Life Expectancy at Birth is a crude, but still powerful measure of health status trend. It is a critical indicator of progress in health care, public health, and environmental health.*

Walker: (3) The indicator is important because its numerical value (number of years) may be influenced by environmental risk factors that may reduce longevity.

3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (4) Life expectancy is a projection but it is derived from “actual measurements” and is an important measure of trend.

Listorti: (4) It meets the criteria of a good indicator, but it is inappropriate when implied to environmental analyses

Ryan: (3) *The above comments address this. However, to repeat, long-term trends in Life Expectancy at Birth suggest the impact of environmental regulation, control, and clean-up on the overall health status of the nation. The measure is crude in that it reflects more than just the environmental impact. Nevertheless, it is a necessary measure. Because of the crudeness at representing the environment, I have downgraded this measure from 4 to 3.*

Walker: (3) The trend of this indicator over time may illuminate change in environmental risk factors. In the literature on health status there is frequent reference to improvements in longevity and factors contributing to those improvements in the U.S. At the same time, stagnating life expectancy in some developing country is discussed with some attention to the environmental causes.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (2)
Ryan: (4)
Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- e) The data are comparable across time and space, and representative¹ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

Please Explain:

Goldman: [no answer provided]

Listorti: Whereas the data do not necessarily show environmental causalities, they are validly collected and maintained, and it should be kept as an indicator to be able to see the larger picture.

Ryan: *The measure meets all of the criteria.*

Walker: The data are derived from the best available data bases, recognizing that most data sets are neither complete nor completely accurate. Each has problems and issues related to completeness, accuracy, and timeliness.

5) Do you have any suggestions for more effective graphic presentation of the data?

¹ An indicator seeks to describe trends in an overall target "population" (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

If yes, please describe.

Goldman: I suggest that race/ethnic trends be presented separately. There are large racial disparities, which are likely to have some relationship to differences in environmental conditions.

Listorti: Yes. If other information show potential linkages to environmental factors, they should be described in the overall report as actual or potential trends.

Ryan: *The trends presented are sufficient to tell the story.*

Walker: [no answer provided]

- 6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: Data should be presented for American Indians/Alaskan Natives.

Listorti: [no answer provided]

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

Walker: [no answer provided]

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD with the modifications identified above.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD.

Walker: X Should be included in ROE06 TD.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **Infant Mortality**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (4)

Listorti: (4) Infant mortality is a valid indicator for overall trends, but it includes too many variables that are not related to environmental conditions.

Ryan: (4) *Infant Mortality is a good indicator of overall maternal and infant health. It is not, however, specific to any environmental insult, but rather includes genetic problems, accidents, etc. If the focus is to be on environmental issues, a more precise estimate that eliminates, for example, accidental deaths, homicides, and suicides, might be a better choice. Further, more finely tuned statistics, including for example deaths whose causes may be inferred to be associated with environmental insult may prove more precise.*

Walker: (3) Among the best indices of community health is the infant death rate because of its relation to a diversity of community services and environmental factors. As a proxy for infant health, the indicator answers the important question in evaluating human health: what proportion of the overall death rate is due to infants under one year of age.

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (4)

Listorti: (2) Too many variables not related to environment

Ryan: (4) *The specific question to be addressed by the Group 1 indicators is “What are the trends in health status in the US?” Infant Mortality is a crude, but still powerful measure of health status trends. It is a critical indicator of progress in health care, public health, and environmental health. Such a measure must be included. However, as discussed above, more precise measures can be envisioned.*

Walker: (3) This indicator is of increasing importance in view of the growing recognition that fetus neonates have heightened susceptibility to certain environmental toxicants including carcinogens. Factors that may increase fetal vulnerability includes high rate of cell proliferation and greater number of target cells at risk.

3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1
Doesn't meet
the definition

2
Only partly
meets the definition

3
Largely meets
the definition

4
Fully meets
the definition

Goldman: (4)

Listorti: (4) It meets the criteria of a good indicator, but it is inappropriate when implied to environmental analyses

Ryan: (3) *The above comments address this. However, to repeat, long-term trends in Infant Mortality suggest the impact of environmental regulation, control, and clean-up on the overall health status of the nation. The measure is crude in that it reflects more than just the environmental impact. Nevertheless, it is a necessary measure. Because of the crudeness at representing the environment, I have downgraded this measure from 4 to 3.*

Walker: (3) This indicator is a numerical value whose trend over time: may illuminate underlying environmental conditions, including increase or decline in exposure to environmental factors

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (2)

Ryan: (4)

Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)
Walker: (3)

- e) The data are comparable across time and space, and representative² of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

Please Explain:

Goldman: [no answer provided]

Listorti: It is an excellent indicator of overall trends, which could include environmental factors, but not directly useful to showing environmental causality

Ryan: *The measure meets all of the criteria.*

Walker: In terms of data quality, the indicator is derived from the best available data bases, despite its limitations.

² An indicator seeks to describe trends in an overall target "population" (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

- 5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: I suggest that race/ethnic trends be presented separately. There are large racial disparities, which are likely to have some relationship to differences in environmental conditions. Data should be presented for American Indians/Alaskan Natives, African Americans, and Asians. There should be a separate presentation of Hispanic/non-Hispanic data.

Listorti: Report should summarize environmental linkages when they are available.

Ryan: *The trends presented are sufficient.*

Walker: [no answer provided]

- 6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: The “What the Data Show” section has a focus on birth defects as a cause of infant mortality. However, disorders related to short gestation and low birthweight are the most significant cause for certain minority populations (e.g. African Americans and American Indians/Alaskan Natives) and this point should be brought out. Also, sudden infant death syndrome should be brought out more clearly including what is known about the role of environment.

The R.O.E. indicator QA/QC discussion should bring out the point that there are numerous variations in these data. Some of these include: (1) whether deaths are coded as fetal deaths or infant mortality in the case of stillbirth and (2) coding of cause of death. The writeup under T4Q4 for cancer mortality for this indicator is excellent and is the kind of discussion that I think is needed for this mortality variable.

Listorti: Probably some of the best data available are on infant mortality. The shortcomings apply to the interpretation of causes, especially those that pertain to poverty, e.g., poor pre-/post-natal care, housing, nutrition, etc. However, these factors are poorly integrated. Need to be better able to distinguish underlying cause as opposed to a “default” category of death, e.g., the broad range of socioeconomic determinants related to poor pre-natal education, poverty, populations that don’t speak English, poor living conditions, income, unemployment, education levels of parents, language spoken at home, etc.

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the*

sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.

Walker: [no answer provided]

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD with the modifications identified above.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD.

Walker: X Should be included in ROE06 TD.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **General Mortality**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (4)

Listorti: (4) General mortality is a valid indicator for overall trends, but it includes too many variables that are not related to environmental conditions.

Ryan: (4) *General Mortality is a good indicator of overall health. It is not, however, specific to any environmental insult, but rather includes genetic problems, accidents, etc. If the focus is to be on environmental issues, a more precise estimate that eliminates, for example, accidental deaths, homicides, and suicides, might be a better choice. Further, more finely tuned statistics, including for example deaths whose causes may be inferred to be associated with environmental insult may prove more precise.*

Walker: (2) The general mortality rate usefulness is limited because it is not sensitive to differences in age distribution within the population. Examination of the trend of the general death rate alone does not do full justice to development related to environmentally related disease. However, mortality is an index of severity of a human health problem from both clinical and environmental/public health standpoint. Mortality can also be used as an severity of disease. When a disease is mild and not fatal, mortality is not a good index of incidence. A mortality rate is a good reflection of incidence rate under certain conditions. For example, cancer of the pancreas is a highly lethal disease; death generally occurs within a few months. Thus, mortality from pancreatic cancer is a good surrogate for the incidence of the disease.

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (4)

Listorti: (2) General mortality contains too many variables not related to environment

Ryan: (4) *The specific question to be addressed by the Group 1 indicators is “What are the trends in health status in the US?” General Mortality is a crude, but still powerful measure of health status trends. It is a critical indicator of progress in health care, public health, and environmental health. Such a measure must be included. However, as discussed above, more precise measures can be envisioned.*

Walker: (2) The indicator contribution is small because it simply reflects the number of deaths with no specification of diagnosis and thus deaths from an environmentally-related disease.

3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (4)

Listorti: (4) It meets the criteria of a good indicator, but it is inappropriate when implied to environmental analyses

Ryan: (3) *The above comments address this. However, to repeat, long-term trends in General Mortality suggest the impact of environmental regulation, control, and clean-up on the overall health status of the nation. The measure is crude in that it reflects more than just the environmental impact. Nevertheless, it is a necessary measure. Because of the crudeness at representing the environment, I have downgraded this measure from 4 to 3.*

Walker: (2) The indicator is a numerical value but it may not illuminate underlying environmental conditions because of its lack of specificity -- age, cause of death and other restrictions.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (2)

Ryan: (4)

Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)
Walker: (3)

- e) The data are comparable across time and space, and representative³ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

Please Explain:

Goldman: [no answer provided]

Listorti: It is an excellent indicator of overall trends, which could include environmental factors, but not directly useful to showing environmental causality

Ryan: *The measure meets all of the criteria.*

Walker: The indicator is derived from the best available data base despite its limitations.

³ An indicator seeks to describe trends in an overall target “population” (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

- 5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: I suggest that race/ethnic trends be presented separately. There are large racial disparities, which are likely to have some relationship to differences in environmental conditions. Data should be presented for American Indians/Alaskan Natives, African Americans, and Asians. There should be a separate presentation of Hispanic/non-Hispanic data.

Additionally I suggest that the data be split by age groups. There is a lot of information that is lost by presenting just non-infant population wide mortality. I would suggest presenting these data in five age groups (consistent with asthma): 1-17y; 18-44y; 45-64 and 65-74 and 75+. Alternatively some of these could be combined, e.g., 18-64 and 65+.

Listorti: Report should summarize environmental linkages when they are available.

Ryan: *The overall trends presented are informative. A similar presentation for the Leading Causes would be informative as well. We have here but a single point in time. Further, a trend line similar to those shown on a year-by-year basis for other indicators would be especially useful for specific causes of mortality that may be associated with environmental measures (See Fig 211.2.) For example, Cancer mortality may be parsed according to those concerns with known, or expected, environmental causes, and those deaths plotted as a temporal trend. The measures plotted now are only for the year 2002 and are, therefore, inconsistent with the plots for other indicators.*

Walker: [no answer provided]

- 6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: The introduction to this indicator should make a stronger point about the role of smoking as well as other preventable causes of death other than environmental exposures.

The R.O.E. indicator QA/QC discussion should bring out the point that there are numerous variations in the coding of cause of death. The writeup under T4Q4 for cancer mortality for this indicator is excellent and is the kind of discussion that I think is needed for this mortality variable.

Also it is important to note that there are great uncertainties in intercensal population estimates and these can impact conclusions about trends in data.

Listorti: [no answer provided]

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

Walker: [no answer provided]

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD with the modifications identified above.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD.

Walker: X Should *not* be included in ROE06 TD.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
 Indicator Name: **Cancer Incidence & Mortality**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (1[mortality]/4[incidence]) As discussed under the “general comments” section I think that the incidence but not the mortality data are appropriate and useful. Trends in mortality for cancer have been largely shaped by improvements in treatment and that is not a reflection of the health of the environment.

Listorti: (4) Excellent for overall picture of human health, but only partially useful for environmental causalities.

Ryan: (4) *Cancer Incidence and Mortality is an excellent indicator of overall health, especially in light of the fraction of individuals who lose their lives to this disease. It is not, however, specific to any environmental insult, but rather includes genetic problems, non-environmental exposures, etc. Further, more finely tuned statistics, including for example deaths whose causes may be inferred to be associated with environmental insult may prove more precise. It may be argued, however, that most cancers are caused by environmental exposures of some kind and even those with a genetic component are likely to be influenced by such exposures.*

Walker: (3) The indicator reflects the impact of cancer on the population, including new cases of the disease and thus is useful in evaluating human health. Moreover, the incidence is a measure of events (i.e., transition from a nondisease to a disease state) the indicator is a measure of risk, which is also a contribution to the overall picture of human health.

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (1[mortality]/4[incidence]) See comment (1)

Listorti: (3) Important, but not critical, because too many causes of cancer are not based on environmental factors

Ryan: (4) *The specific question to be addressed by these Group 1 indicators is “What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?” Cancer Incidence and Mortality is a crude, but still powerful, measure relevant to this question. Many cancers are thought to be environmental in origin and gene-environment interaction may account for a significant portion of the remainder. Because of this, such a measure must be included in a set of indicators. However, as discussed above, more precise measures can be envisioned.*

Walker: (3) The indicator covers an area of increasing importance, as interest in the “carcinogenic outcome” of gene-environment interactions intensifies. It is generally accepted that approximately 80 percent of all cancers have an environmental component. However general cancer incidence and mortality rates mask the variation in incidence and mortality of cancers according to organs where the abnormal cellular growth begins. Some of these variations may be due to variations in environmental exposure. Further cancer cannot be considered a single disease: rather it is collection of more than 100 separate conditions. These afflictions frequently have different causes, clinical manifestations and natural histories.

3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn’t meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (1[mortality]/4[incidence]) See comment (1)

Listorti: (4) Well maintained, accurate data base.

Ryan: (3) *The above comments address this. However, to repeat, long-term trends in Cancer Incidence and Mortality suggest the impact of environmental regulation, control, and clean-up on the overall health status of the nation and in diseases impacted by the environment. The measure is crude in that it reflects more than just the environmental impact. Nevertheless, it is a*

necessary measure. Because of the crudeness at representing the environment, I have downgraded this measure from 4 to 3.

Walker: (3) The indicator is a numerical value whose trend may illuminate underlying trends in environmental conditions including the extent of exposure to known or suspected carcinogenic agents.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (1[mortality]/4[incidence])

Listorti: (3)

Ryan: (4)

Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

e) The data are comparable across time and space, and representative⁴ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

Please Explain:

Goldman: See comment (1)

⁴ An indicator seeks to describe trends in an overall target "population" (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

Listorti: Probably one of the best data bases out there, but doesn't necessarily show environmental causalities.

Ryan: *The measure meets all of the criteria.*

Walker: Data base from which the indicator is derived is the best available, despite its well known limitations.

5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: If you *must* present the mortality data it should be secondary to the incidence data (rather than presenting it first, which makes it appear to be the more relevant indicator).

The data for regional rates are not clearly readable. I would suggest perhaps using a more vertical graphic presentation that would give more separation to the rates from regions.

Also there appears to be an error for the map since there are no "green" areas mapped. The map should indicate the basis for the four categories. (I.e., are these quartiles?)

I suggest that race/ethnic trends be presented separately. There are large racial disparities, which are likely to have some relationship to differences in environmental conditions. Data should be presented for African Americans, and any other major race/ethnic groups for which there are valid data.

Listorti: Explicitly show actual and possible environmental linkages

Ryan: *The overall trends presented are informative. However, the presentation by EPA Region is less so. While perhaps of use to EPA, a more informative presentation would include a state-by-state presentation. The sharp peak in the early 90s for males deserves some discussion.*

Walker: [no answer provided]

6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: The introduction to this indicator should make a stronger point about the role of smoking as well as other preventable causes of cancer other than environmental exposures.

It is important to note that there are great uncertainties in intercensal population estimates and these can impact conclusions about trends in incidence and mortality data.

Listorti: When environmental linkages are clear, they should be explained. Data may not adequately show causes of multiple sources or cumulative effects. Nor do they indicate importance of socioeconomic factors like diet/nutrition, access to medical care for early detection, etc. Data from other sources could be examined for application to humans, e.g., wildlife biology, but this is not done systematically. Also, selected occupational data from developing countries might be helpful to understanding overall US exposures because they help overcome the time lag and mobility problems because of the concentrations of exposures, e.g., women working in the electronics industry in Asia.

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

Walker: The indicator should be modified to reflect concerns about organ specific cancers, consistent with the usual cancer classification system (according to site of initial abnormal cellular growth). A few major types of cancer for which there is substantial evidence of a causal association with physical or chemical environmental agents and/or industrial processes, should be included as indicators.

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD with the modifications identified above.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD.

Walker: X Should be included in ROE06 TD with the modifications identified above.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **CVD Mortality**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (4) See my general comments. I think that the report should include prevalence of cardiovascular disease (ischemic heart disease, stroke and hypertension) as well as mortality. Note that because ambient air pollution triggers mortality from cardiovascular disease, I think that it is important for the ROE to track both prevalence and mortality of this condition and that the data are available to do so.

Listorti: (4) Excellent for human health, but only partially useful for environmental causalities.

Ryan: (4) *Cardiovascular Disease Mortality is an excellent indicator of overall health, especially in light of the fraction of individuals who lose their lives to this disease. It is not, however, specific to any environmental insult, but rather includes genetic problems, non-environmental exposures, etc. Further, more finely tuned statistics, including for example deaths whose causes may be inferred to be associated with environmental insult may prove more precise. Recent epidemiological evidence has supported a link between environmental exposures, especially those to particulate matter, and CVD. A more finally honed presentation may cast more light on this interesting finding.*

Walker: (3) The indicator answers the question: what proportion of all deaths are due to cardiovascular disease? As a proxy for health, CVD mortality indicator contributes to the overall picture of health and evaluating human health.

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (4)

Listorti: (3) Important, but not critical, because too many causes of CVD are not based on environmental factors

Ryan: (4) *The specific question to be addressed by these Group 1 indicators is “What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?” CVD Mortality is a crude, but still powerful, measure relevant to this question. As discussed in note 1), some environmental exposures are thought to be associated with CVD. Further, gene-environment interaction may account for a significant portion of the risk for CVD. Because of this, such a measure must be included in a set of indicators. However, as discussed above, more precise measures can be envisioned.*

Walker: (3) CVD disease encompasses a number of diverse heart and blood vessel diseases. The weight of evidence points to environmental risk factors for CVD. The most-cited Six Cities study found substantial evidence of an association between air pollution and CVD. Studies since then have recorded similar findings.

3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (4)

Listorti: (4) Well maintained, accurate data base.

Ryan: (3) *The above comments address this. However, to repeat, long-term trends in CVD Mortality suggest the impact of environmental regulation, control, and clean-up on the overall health status of the nation and in diseases impacted by the environment.. The measure is crude in that it reflects more than just the environmental impact. Nevertheless, it is a necessary*

measure. Because of the crudeness at representing the environment, I have downgraded this measure from 4 to 3.

Walker: (3) Indicator is a numerical value. The trend over time is likely to illuminate underlying environmental trends.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (3)
Ryan: (4)
Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

e) The data are comparable across time and space, and representative⁵ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

Please Explain:

Goldman: [no answer provided]

⁵ An indicator seeks to describe trends in an overall target "population" (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

Listorti: Probably one of the best data bases out there, but doesn't necessarily show environmental causalities.

Ryan: *The measure meets all of the criteria.*

Walker: The indicator is derived from the best available data base despite its limitations.

5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: I suggest that race/ethnic trends be presented separately. There are large racial disparities, which are likely to have some relationship to differences in environmental conditions. Data should be presented for African Americans, and any other major race/ethnic groups for which there are valid data.

Why not include a map, as for cancer mortality?

Listorti: Explicitly show actually and possible environmental linkages

Ryan: *The overall trends presented are informative. However, the presentation by EPA Region is less so. While perhaps of use to EPA, a more informative presentation would include a state-by-state presentation. It is interesting to note the near-parallel trend lines suggesting nationwide reduction in CVD Mortality rates. However, finer inspection does indicate some structure. Exploration of these differences would be of interest. Since these are age-adjusted, it seems more likely that the differences are environmentally related.*

Walker: [no answer provided]

6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: The introduction to this indicator should make a stronger point about the role of smoking as well as other preventable causes of CVD mortality other than environmental exposures.

The R.O.E. indicator QA/QC discussion should bring out the point that there are numerous variations in the coding of cause of death. The write-up under T4Q4 for cancer mortality for this indicator is excellent and is the kind of discussion that I think is needed for this mortality variable.

Also it is important to note that there are great uncertainties in intercensal population estimates and these can impact conclusions about trends in data.

Listorti: When environmental linkages are clear, they should be explained. Generally, data do a good job on coverage, but not necessarily on environmental linkages, especially for diet and the linkages to pollution which are still poorly established. In fact, the stress on cholesterol (as opposed to balanced diet) may divert attention away from environmental linkages because the public gets confusing messages that often seem contradictory and do not stress the broader context to show environmental linkages to nutrition, pollution exposures, and living conditions. Lots of basic nutrition data exist that could be analyzed for prevention of heart disease. Need better methods to distinguish cardiovascular deaths as a “default” category of mortality without necessarily showing causality, e.g. old age, poor nutrition, stress, etc. We should take a closer look at advertising practices of the private sector which generally create a positive image of their product without showing any of the public health risks, ranging from automobiles to nutrition.

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

Why are 1999 data missing from the trend lines?

Walker: [no answer provided]

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD with the modifications identified above.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD.

Walker: X Should be included in ROE06 TD.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **Asthma Prevalence & Mortality**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (1[mortality]/4[prev]) As discussed under the “general comments” section I think that the prevalence but not the mortality data are appropriate and useful. Trends in mortality for asthma have been largely shaped by improvements in treatment and that is not a reflection of the health of the environment.

Listorti: (4) Reasonably good database in general.

Ryan: (3) *Asthma Prevalence and Mortality is not a good indicator of overall health, but is an important indicator of the impact of environment on health as asthma attacks can be triggered by environmental insult. The data as reported are not, however, specific to any environmental specific to an measured insult, and include specific genetic association and effects of non-environmental exposures, such as exercise. Further, more finely tuned statistics, including for example deaths whose causes may be inferred to be associated with environmental insult may prove more precise. Examples may include asthma attacks on days with high ozone or particulate, or in setting known for the presence of aeroallergens. A more finally honed presentation may cast more light on this important topic.*

Walker: (3)

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (1[mortality]/4[prev]) See comment (1)

Listorti: (3) Important rather than critical because many sources of asthma are not environmental

Ryan: (4) *The specific question to be addressed by these Group 1 indicators is “What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?” Asthma Incidence and Mortality is a crude, but still powerful, measure relevant to this question. As discussed in note 1), some environmental exposures are thought to be associated with asthmatic attacks. Further, gene-environment interaction may account for a significant portion of the risk for developing asthma initially and severity of attacks that may occur. Because of this, such a measure must be included in a set of indicators. However, as discussed above, more precise measures can be envisioned.*

Walker: (3) The indicator makes an important contribution to answering the specific ROE question because it reflects the number of people affected in the population at a specific time. Further, the indicator reflects a slice through the population at a point in time at which it is determined who has asthma and who does not. In addition, asthma mortality answers the question: what proportion of all deaths are due to asthma. As a proxy for health, asthma mortality (index) contributes to the overall picture of health and is useful to evaluating human health.

3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (1[mortality]/4[prev]) See comment (1)

Listorti: (4) Excellent information with potential links to environmental causalities

Ryan: (3) *The above comments address this. However, to repeat, long-term trends in Asthma Incidence and Mortality suggest the impact of environmental regulation, control, and clean-up on the overall health status of the nation and in diseases impacted by the environment. The measure is crude in that it reflects more than just the environmental impact. Nevertheless, it is a necessary measure. Because of the crudeness at representing the environment, I have downgraded this measure from 4 to 3.*

Walker: (3) Indicator is a numerical value. The trend over time may illuminate underlying environmental trends. This is because there is substantial evidence that environmental agents may trigger and asthmatic response.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (1[mortality]/4[prev])

Listorti: (4)

Ryan: (4)

Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (3)

Listorti: (4)

Ryan: (4)

Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (3)

Listorti: (4)

Ryan: (4)

Walker: (3)

e) The data are comparable across time and space, and representative⁶ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (2)

Listorti: (4)

Ryan: (4)

Walker: (3)

f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

Please Explain:

Goldman: For mortality, see my comments above in (1). For prevalence, the data are based on self reports of physician diagnosed asthma so there is some element of recall involved. Also

⁶ An indicator seeks to describe trends in an overall target "population" (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

there is some variability in diagnosis of asthma. In terms of comparisons across space and time it is of course relevant that the NHIS changed the asthma questions on its survey in 1997, however, the data have been collected consistently since that time.

Listorti: The asthma database generally is good, and the potential linkages to environment high.

Ryan: *A significant fraction of asthmatic attack and perhaps even the etiology of asthma suggest that the environment is an important component. Hence this measure is important. Further, the measure meets all of the criteria outlined above.*

Walker: The indicator is derived from the best available data base despite its limitations.

5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: The graphic for asthma mortality is not helpful; these are rare events and by breaking it down into regions a lot of the differences between regions are obscured. If you must report the mortality data (and I recommend not) then I would suggest something like a five-year moving average or perhaps taking it to a larger level such as the four PHS regions.

I suggest that race/ethnic trends for asthma prevalence be presented separately. There are large racial disparities, which are likely to have some relationship to differences in environmental conditions. Data should be presented for African Americans, and any other major race/ethnic groups for which there are valid data. Such data could be tabulated with perhaps a prevalence rate and 95% confidence intervals.

The EPA should consider using a figure for asthma in adults like the Figure 094 in the childhood asthma indicator.

Listorti: When environmental relationships are clear, they should be highlighted.

Ryan: *The overall trends presented are informative and useful. However, the presentation by EPA Region is less so and are quite difficult to follow in the presentation of Figure 081. The Mortality rates for each Region cross repeatedly and those with similar colors are difficult to distinguish. I would suggest a different presentation. While perhaps of use to EPA, a more informative presentation would include a state-by-state presentation. Since these are age-adjusted, it seems more likely that the differences are environmentally related.*

Walker: [no answer provided]

- 6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: The introduction should take note of air pollution as an environmental trigger!

It is important to note that there are great uncertainties in intercensal population estimates and these can impact conclusions about trends in prevalence and mortality data.

Listorti: There has been a global increase in asthma, but the reasons are still not certain. Updates on causality would be helpful to see if the reasons for causality are now clearer. In addition, available data do not adequately reflect socioeconomic factors like poverty, poor housing, and indoor air pollution, which are environmentally based.

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

The smoothed curves in Figures 82-1 and 82-1 may mislead in that there are only the points given in the graph, not the curvature between points that the spline-like fit might suggest.

Walker: [no answer provided]

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD with the modifications identified above.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD.

Walker: X Should be included in ROE06 TD.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **COPD Mortality**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (4) I think that the term “chronic lung disease” might be more “user friendly” for the public than “COPD”. As in the case with cardiovascular disease, the report should include prevalence of chronic lung disease as well as mortality. These data are available via the National Health Interview Survey. Note that because ambient air pollution triggers mortality from chronic lung disease, I think that it is important for the ROE to track both prevalence and mortality of this group of conditions

Listorti: (3) Not sure how well COPD is reflected in cases that are non-life threatening in poorer populations of inner cities, rural areas and with populations that don’t speak English. Mortality is covered well, but not sure about morbidity. In both cases, environmental factors are not stressed as the main cause, especially relative to indoor air pollution and occupational exposures.

Ryan: (3) *Chronic Obstructive Pulmonary Disease (COPD) Mortality may a good indicator of overall health, but its importance as an important indicator of the impact of environment on health is less clear. The data as reported are not specific to any specific insult, and include specific genetic association and effects of non-environmental exposures, such as exercise and workplace environment. Further, more finely tuned statistics, including for example deaths whose causes may be inferred to be associated with environmental insult may prove more precise. Examples may include COPD-related deaths on days with high ozone or particulate, or in setting known for the presence of aeroallergens or other lung irritants. A more finally honed presentation may cast more light on this important topic.*

Walker: (3) The term COPD encompasses chronic obstructive bronchitis, with obstruction of small airways, and emphysema, with enlargement of air spaces and destruction of lung tissue, lung elasticity, and closure of small airways. The mortality from these disorders is a proxy for health. Thus the indicator is useful for evaluating human health and for contributing to the overall picture of health.

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it

makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (4)

Listorti: (3) As above

Ryan: (4) *The specific question to be addressed by these Group 1 indicators is “What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?” COPD Mortality is a crude, but still powerful, measure relevant to this question. As discussed in note 1), some environmental exposures are thought to be associated with COPD mortality.*

Further, gene-environment interaction may account for a significant portion of the risk for developing COPD initially and severity of any disability that may occur. Because of this, such a measure must be included in a set of indicators. However, as discussed above, more precise measures can be envisioned.

Walker: (3) The indicator is important because it covers an area important environmentally. In industrialized countries cigarette smoking accounts for most cases of COPD. Environmental pollutants such as particulates are important causes. Air pollution(particularly sulfur dioxide and cadmium) may all be risk factors. It is likely that an environmental exposure interacting with genetic predisposition will result in COPD

3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (4)

Listorti: (3) It is not clear how accurate the data are. Data area reasonably well collected data for those cases that are caught by the medical care system. Not sure how much goes

undiagnosed, especially in populations that don't see a physician regularly and in medium and small businesses where there are no systematic reporting of such factors.

Ryan: (3) *The above comments address this. However, to repeat, long-term trends in COPD Mortality suggest the impact of environmental regulation, control, and clean-up on the overall health status of the nation and in diseases impacted by the environment. The measure is crude in that it reflects more than just the environmental impact. Nevertheless, it is a necessary measure. Because of the crudeness at representing the environment, I have downgraded this measure from 4 to 3.*

Walker: (3) The indicator is a numerical value whose trend over time may raise concerns about underlying environmental conditions because virtually all respiratory symptoms can be environmentally (occupational and nonoccupational) related.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, "important" means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (3)

Ryan: (4)

Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (3)

Ryan: (4)

Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (3)

Ryan: (4)

Walker: (3)

d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (3)

Ryan: (4)

Walker: (3)

e) The data are comparable across time and space, and representative⁷ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (3)

Ryan: (4)

Walker: (3)

f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

⁷ An indicator seeks to describe trends in an overall target "population" (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

Listorti: (3)

Ryan: (4)

Walker: (3)

Please Explain:

Goldman: [no answer provided]

Listorti: Reasonably good data because it deals with chronic illness

Ryan: *A significant fraction COPD and perhaps even its etiology suggest that the environment is an important component. Hence this measure is important. Further, the measure meets all of the criteria outlined above.*

Walker: Indicator is derived from the best available data base despite its limitations.

5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: I suggest that race/ethnic trends for COPD mortality be presented separately. There are large racial disparities, which are likely to have some relationship to differences in environmental conditions. Data should be presented for African Americans, and any other major race/ethnic groups for which there are valid data.

There appears to be an error for the map since there are no “green” areas mapped. The map should indicate the basis for the four categories. (I.e., are these quartiles?)

Listorti: [no answer provided]

Ryan: *The overall trends presented are informative and useful. However, the presentation by EPA Region is less so and are quite difficult to follow in the presentation of Figure 080-1. The Mortality rates for each Region cross repeatedly and those with similar colors are difficult to distinguish. I would suggest a different presentation. While perhaps of use to EPA, a more informative presentation would include a state-by-state presentation. Since these are age-adjusted, it seems more likely that the differences are environmentally related.*

Walker: [no answer provided]

6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: It is important to note that there are great uncertainties in intercensal population estimates and these can impact conclusions about trends in incidence and mortality data.

Listorti: Would be helpful to pay more attention to socioeconomic and behavioral determinants, especially in poorer populations. For example, not sure how well the connection between indoor air pollution is made and occupational exposures in medium and small businesses where there are no systematic reporting of such factors. Not sure how well they are reflected in cases that are non-life threatening in poorer populations of inner cities, rural areas, and with populations that don't speak English. Mortality is covered well, but not morbidity. In both cases, environmental factors are not stressed as the main cause, especially relative to indoor air pollution and occupational exposures.

Housing quality and occupational exposures in small/cottage industries, agriculture, domestic work (housecleaning) and other jobs which entail manual labor could be helpful in providing better understanding of populations at risk. It would be possible to develop lists of products which cause air pollution, ranging from household uses to agriculture/gardening, and increase exposure risks.

Housing quality and labor statistics could be used to determine high risk groups, which, in turn, could be used as short-lists of high risk groups to whom we could better direct preventive measures.

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

Walker: [no answer provided]

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD with the modifications identified above.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD.

Walker: X Should be included in ROE06 TD.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**

Indicator Name: **Infectious Gastrointestinal and Arthropod-Borne Disease Prevalence**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (4) I think that this indicator should be split into two pieces: infectious gastrointestinal as one indicator and arthropod-borne disease as a second indicator. There are a number of additional infectious agents that I think should be considered as follows:

Malaria: Why is malaria excluded from the list of arthropod borne diseases? There are still many cases each year in the US, more than for Rocky Mountain spotted fever, which is included.

Giardia: Why is giardiasis excluded from the list of enteric diseases? It is a significant environmental parasite and far more prevalent than another protozoan cryptosporidia that is included.

Legionella: Another omission is legionella infection. Often associated with indoor air contamination it is a significant environmental pathogen and of high enough prevalence to be important nationally.

Viral encephalitis: It may be worth including mosquito borne viral encephalopathies other than West Nile virus (e.g. California serogroups)?

Listorti: (4) Excellent indicator of changing role of climate change and global warming, which has been underrepresented in EPA statistics.

Ryan: (2) *Infectious Gastrointestinal and Arthropod-Borne Disease Prevalence represents two classes of indicators. Infectious Gastrointestinal Prevalence is a good indicator of overall water quality, but the number of cases suggests that it is not a good indicator of overall human health. Its importance as an important indicator of the impact of environment on health is clearer. The data as reported are specific to an environmental insult, namely the presence of infective materials in water. The case for Arthropod-Borne Disease Prevalence is weaker and is more likely to be indicative of local weather conditions than the general picture of human health.*

Walker: (3) Gastrointestinal infectious disease continues to be a serious burden around the world, in developing and industrialized countries alike. Microbial agents can cause illness, disability and death

while disrupting entire population. In the highly interconnected and readily traversed “global village” of this period, one nation’s GI infection soon becomes every nation’s problem as geographical boundaries offer trivial impediment to such threats. Thus the indicator is AA&U.

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (4)

Listorti: (4) Excellent indicator of changing role of climate change and global warming, which has been underrepresented in EPA statistics.

Ryan: (2) *The specific question to be addressed by these Group 1 indicators is “What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?” Infectious Gastrointestinal and Arthropod-Borne Disease Prevalence are likely to be of interest in limited regions and limited times. The total number of cases for many of this diseases is quite small and of less general importance than other indicators in this group.*

Walker: (3) The indicator covers an area of increasing importance, given the convergence of any number of factors that can create environmental conditions in which infectious diseases emerges and become rooted in society. Pathogens transmitted by mosquitoes and their arthropod allies sicken million of people each year. Of 10 diseases targeted by the World Health Organization for special control programs, seven are arthropod-borne.

- 3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn’t meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (4)

Listorti: (3) Data accuracy are problematic, as well as diagnosis of illnesses. Many US doctors are unaware of vector-borne diseases because generally they're rare here.

Ryan: (4) *Although likely to be limited in geographical and temporal scope, this indicator does draw attention to the underlying condition of the environment on such locations and at the time. Presence of breeding grounds for the infectious elements or disease-carrying insects can be evaluated using these data.*

Walker: (3) The indicator is a numerical value whose trend over time may illuminate underlying trends in conditions of the environment, including water quality, food sanitation, and ecological changes that can alter the replication and transmission pattern of infectious organism. A growing number of emerging infectious diseases arise from human contact with animal reservoirs as result of changing land use patterns.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, "important" means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (2)

Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (3)

Listorti: (3)

Ryan: (4)

Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (3)
Listorti: (3)
Ryan: (4)
Walker: (3)

- d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- e) The data are comparable across time and space, and representative⁸ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet	Only partly	Largely meets	Fully meets

⁸ An indicator seeks to describe trends in an overall target "population" (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

this criterion at all

meets this criterion

this criterion

this criterion

Goldman: (4)

Listorti: (3)

Ryan: (4)

Walker: (3)

Please Explain:

Goldman: Although the reporting of “reportable diseases” is less than perfect there are studies over the years that show that such data do provide a valid basis for assessment of trends across time and regions in the US.

Listorti: Important information, by any standards, but data bases in US are somewhat problematic because the diseases are either rare, e.g. , malaria, or generally not serious, e.g. ,food poisoning. These disease sets are most common in developing countries.

Ryan: *This indicator is not sufficiently general to meet the criterion as outlined. However, it does meet the objectivity criteria.*

Walker: The indicator is derived from the best available data base, despite its limitations.

5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: This section of the report shows charts of “prevalence” of reported cases. I think it would be clearer to label these as “number” of reported cases. These two charts give data on a log scale, which I think is likely to be misleading to a majority of readers in that large changes in numbers at the top appear small and small changes in numbers at the bottom appear large. I suggest using tables instead of graphs.

Listorti: When environmental linkages are clear, they should be highlighted in reports.

Ryan: *The logarithmic scale used in presenting the data in Figures 083-089 Arthropod and 083-89 GI provide insufficient detail to be useful. It can be seen that Lyme Disease is more prevalent the Rocky Mountain Spotted Fever, for example, but trends in annual prevalence are obscured. This problem stems from attempting to put all graphs on the same scale. Alternative presentations should be considered.*

Walker: [no answer provided]

- 6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: [no answer provided]

Listorti: In general, arthropod-borne and infectious gastrointestinal diseases are not well known in this country, but of are increasing importance. Relatively speaking, pollution, especially industrial and vehicular, dominates the environmental agenda and we need to offset that imbalance. By comparison, climate change and global warming issues in this country are in their infant stage when compared with the rest of the world. The general public is not well sensitized to risks and not sure if physicians are adequately sensitized as well to diagnose the vector-related diseases unless they already have come in contact with it or it is already a well-publicized *local* problem, like Lyme disease. Similarly, gastrointestinal diseases covers a broad category and it is not sure how much is misdiagnosed as food-poisoning when they should be diagnosed as gastrointestinal from other sources, such as poor hygiene. A select portion of the population potentially affected by the diseases tend to be well represented by statistics, but it is not clear how many are not diagnosed at all, especially in rural areas with poor health coverage. The indicator doesn't necessarily reflect *recreational* exposures (camping, hiking, golf), as opposed to general risk, e.g., for West Nile virus.

Considerable environmental and ecological information already exists that could be used to determine risks for the vector-related diseases, such as vector distribution and weather data that can indicate possibility for increased breeding of the vectors. Similarly, popular recreational areas, such as golf courses and hiking/camping areas are also available so as to facilitate public awareness. Suburban housing construction could also provide a short list of possible risks.

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

Walker: [no answer provided]

- 7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD with the modifications identified above.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should *not* be included in ROE06 TD.

Walker: X Should be included in ROE06 TD.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **Low Birthweight**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (2) Birthweight is a function of growth and gestational age. As constructed, the indicators for low birthweight and for preterm delivery are nearly identical given the strong association between birthweight and weeks gestation; yet, each indicator is supposed to make “an important contribution to answering a question for the ROE”? I suggest you change how you present these data to clearly focus on *growth*. The simplest approach would be to track low birthweight only among term births. A more elaborate approach would be to categorize births as being at or below the 10th percentile for weight for gestational age.

Further, birthweight for gestational age is confounded by many factors but most importantly by age of the mother and whether the birth is single or multiple. Since there have been major trends, in recent years, for rates of birth among women who are very young or toward the end of their reproductive potential (and therefore at highest risk for low birthweight for gestational age) I recommend that EPA limit this indicator to births to women between the ages of 18-39. Likewise, because use of assisted reproductive technology has had a profound impact on birthweight for gestational, I recommend limiting this indicator to singleton births.[1] By limiting these data to singleton births to women 18-39 these data would be more *comparable across space and time*, a major criterion for this report.

Listorti: (4) Generally, a good data set reflecting overall health conditions.

Ryan: (3) *Low Birthweight is a useful indicator of overall health of both the mother and infant. The indicator would be considered more AA&U if it were controlled for genetic factors including small stature in the mother and small stature in the father. While some characteristics associated with Low Birthweight have strong environmental components, e.g., maternal smoking, others may not.*

Walker: (3) Low birth weight is a component of the spectrum of adverse birth outcomes. Its true magnitude may reflect directly or indirectly human health status. LBW is an important risk factor for neonatal and postneonatal mortality, which is a proxy for health. Thus the indicator is AA&U.

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (4)

Listorti: (2) Too many factors unrelated to environment.

Ryan: (3) *The specific question to be addressed by these Group 1 indicators is “What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?” To the degree to which one believes that Low Birthweight has an environmental association, then the indicator is of importance.*

Walker: (3)

- 3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (2) See the comment above

Listorti: (4) Generally a good database, but not directly pertinent to environment.

Ryan: (2) *There are a number of alternative factors other than environment that might lead to low birthweight. Hence this indicator is not the best for determining trends in underlying environmental conditions.*

Walker: (3)

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (2)

Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- e) The data are comparable across time and space, and representative⁹ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (3)

Ryan: (4)

Walker: (3)

- f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

Please Explain:

Goldman: [no answer provided]

Listorti: Generally a good database, but not directly pertinent to environment.

⁹ An indicator seeks to describe trends in an overall target “population” (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

Ryan: *This indicator is not sufficiently associated with environmental conditions to meet the criterion as outlined fully. However, the objectivity criteria are met.*

Walker: [no answer provided]

5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: I suggest that race/ethnic trends for low birthweight be presented separately. There are large racial disparities, which are likely to have some relationship to differences in environmental conditions. Data should be presented for African Americans, and any other major race/ethnic groups for which there are valid data.

Why not include a map, as for cancer and COPD mortality?

See comments in (1) with regards to focusing only on singleton births to women 18-39.

Listorti: [no answer provided]

Ryan: *The scale used on the graphs is quite wide with respect to the relatively narrow range spanned by the data. I suggest expanding the graph by showing only the 5% to 9% region. Trends are very slight and difficult to see in the current graphs. Further, the colors are hard to distinguish. While perhaps of use to EPA, a more informative presentation would include a state-by-state presentation. Since these are age-adjusted, it seems more likely that the differences are environmentally related.*

Walker: [no answer provided]

6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: [no answer provided]

Listorti: High quality data exist when they from the right mothers, but may miss inner city, poor rural areas, and immigrant communities. The focus on nutrition and pre-/post-natal health care diverts attention from environmental factors, which could be significant, but have not been well established. The populations at risk are already known, with a high prevalence among the poor. The problems lie with outreach and several indicators could be developed to get a better picture of those populations --- for example, foreign language newspapers. census data, income and education levels, single-parent household, lists of church groups and NGO/PVOs working locally, etc.--- and also to improve ways to reach them.

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

Walker: [no answer provided]

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD with the modifications identified above.

Listorti: X Should be included in ROE06 TD with the modifications identified above.

Ryan: X Should be included in ROE06 TD with the modifications identified above.

Walker: X Should be included in ROE06 TD.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**

Indicator Name: **Birth Defects Incidence & Mortality**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (1) Birth certificate data greatly undercount even the birth defects that are immediately diagnosed at birth. Moreover, many significant birth defects are not diagnosable prior to hospital discharge and are not recorded on the birth certificate.[2, 3] Further, birth defects contain a hodgepodge of ICD's that include minor birth defects and deformations as well as major malformations. That is why, as in the case of cancer, birth defects registries have been developed and a national system of birth defects registries, the National Birth Defects Prevention Network (<http://www.nbdpn.org>), created. EPA should work with the NBDPN and the CDC National Center on Birth Defects and Developmental Disabilities to: (1) identify which ICD codes for birth defects merit inclusion; (2) identify registries in the NBDPN to utilize for national data. These should be registries that: have provided stable, timely and consistent data over time and utilize similar methods for case ascertainment (including active methods and use of medical records beyond the newborn exam). In any case, birth defects data are considered to be "prevalence" or "prevalence proportion" statistics and certainly not "incidence", "incidence rate" or "prevalence rates".[4]

As discussed under the "general comments" section the prevalence but not the mortality data are appropriate and useful for birth defects. Trends in mortality for birth defects have been largely shaped by improvements in treatment and not via modifications of risk factors.

Listorti: (4) Generally a good dataset reflecting overall health conditions.

Ryan: (4) *Birth Defects Incidence and Mortality is a very useful indicator of overall health of both the mother and infant. While some characteristics associated Birth Defects Incidence and Mortality with have strong environmental components, e.g., maternal smoking, others may not.*

Walker: (3) Between 2% and 3% of live-born infants are estimated to have major developmental defects. A developmental defect is a structural or functional anomaly that results from alteration in normal development. Thus, it is a health problem which is reflected in the indicator.

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (4)

Listorti: (3) Good info, with many potential linkages to environment.

Ryan: (3) *The specific question to be addressed by these Group 1 indicators is “What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?” To the degree to which one believes that Birth Defects Incidence and Mortality has an environmental association, then the indicator is of importance. Genetic factors also contribute as do the interaction of genetics with exposures experienced in utero. Hence the factor is of great importance, but may not be definitive. This precipitates my downgrading the rating from 4 to 3.*

Walker: (3) The indicator is important because of the continuing concerns about environmentally related developmental defects and their contribution to community health profile. Moreover, advances in the science of developmental toxicology is enhancing our understanding of the influence of environmental toxicants on developmental defects. (NRC 2002)

- 3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (2) This would not be true for the data as presented as explained in the comment above.

Listorti: (3) Too many factors not related to environment.

Ryan: (3) *There are a number of alternative factors other than environment that might lead to an increase or decrease Birth Defects Incidence and Mortality. Hence this indicator is not definitive for determining trends in underlying environmental conditions. However, many conditions can be attributed to environmental or occupational exposures so the indicator is quite useful.*

Walker: (3) Indicator is a numerical value whose long term trend may illuminate related environmental risk factor.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (3)

Ryan: (3)

Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (1)

Listorti: (3)

Ryan: (4)

Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (1)
Listorti: (3)
Ryan: (4)
Walker: (3)

d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (3)
Listorti: (3)
Ryan: (4)
Walker: (3)

e) The data are comparable across time and space, and representative¹⁰ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (1)
Listorti: (3)
Ryan: (4)
Walker: (3)

f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (3)
Ryan: (4)
Walker: (3)

¹⁰ An indicator seeks to describe trends in an overall target “population” (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

Please Explain:

Goldman: Same as comments under (1)

Listorti: Generally good info, but includes many factors not linked to environment.

Ryan: *This indicator is sufficiently associated with environmental conditions to meet the criterion as outlined. The impact of genetic factors mitigates its utility in assessing environmental impact. The objectivity criteria are all met.*

Walker: Indicator is derived from best available data, despite its limitations.

5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: If EPA continues to include birth defect mortality as an indicator, rather than Figure 090-2 a figure showing the major birth defects as causes of mortality in the first year of life as well as over a lifetime would be more informative.

The figure for “leading causes of infant deaths” is repetitive of an earlier figure and should be deleted from this section.

If Table 097 is used it should be clearly stated that these are birth defects as ascertained at birth and recorded on the birth certificate.

Listorti: [no answer provided]

Ryan: *The overall trends presented are informative and useful. However, the presentation by EPA Region is less so and are quite difficult to follow in the presentation of Figure 096. The Mortality rates for each Region cross repeatedly and those with similar colors are difficult to follow. I would suggest a different presentation. Figure 090-2 presents data for only a single year. A more informative figure would show such trends over time. Table 097 presents such information in tabular form.*

Walker: [no answer provided]

6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: The R.O.E. indicator QA/QC discussion is way off the mark for birth defects as recorded on birth certificates. See the papers cited earlier in these comments. T1Q1, T1Q2, and T2Q1 need to point out, respectively, the lack of validity, the lack of soundness and the lack of monitoring and quality control in recording of birth defects on the birth certificate. The comments in T4Q4 are more appropriate.

Listorti: [no answer provided]

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

Walker: The indicator should be developmental defects which includes the full range of kinds and severity of defects and the full range of times of detection – before, at, and after birth.

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD with the modifications identified above.

Listorti: X Should be included in ROE06 TD with the modifications identified above.

Ryan: X Should be included in ROE06 TD with the modifications identified above.

Walker: X Should be included in ROE06 TD with the modifications identified above.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **Childhood Cancer Incidence & Mortality**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (1[mortality]/4[incidence]) I think that the incidence but not the mortality data are appropriate and useful. Trends in mortality for cancer have been largely shaped by improvements in treatment and that is not a reflection of the health of the environment.

Listorti: (4) Generally good info on overall trends and the general health picture.

Ryan: (4) *Childhood Cancer Incidence and Mortality can be a very useful indicator of the environmental influence on overall health. With the exception of genetically linked cancers, environmental exposure in utero or at a very young age may contribute substantially to cancer risk. Further, the time scale over which such exposures can be effective in producing childhood cancers is short affording a better understanding of the link between the environment, genetics, and cancer. While some characteristics associated Childhood Cancer Incidence and Mortality with have strong environmental components, e.g., exposure of the developing fetus or embryo to certain chemicals, others may not. This weakens the utility of the indicator.*

Walker: (3) The indicator reflects the number of new cases, a measure of the disease that develops in persons who did not have the disease and thus contributes to the overall picture of human health.

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (1[mortality]/4[incidence]) See comment (1)

Listorti: (4) Even though there are many factors not related to environmental causality, the relationships are strong enough to call it critical.

Ryan: (3) *The specific question to be addressed by these Group 1 indicators is “What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?” To the degree to which one believes that Childhood Cancer Incidence and Mortality has an environmental association, then the indicator is of importance. Genetic factors also contribute as do the interaction of genetics with exposures experienced in utero. Hence the factor is of great importance, but may not be definitive. This precipitates my downgrading the rating from 4 to 3.*

Walker: (3) Data from case-control studies have suggested that environmental exposure may increase risk of childhood cancer.

3) To what extent do you think the indicator meets the following indicator definition:

*An “indicator” is **a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition** over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.*

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (1[mortality]/4[incidence]) See comment (1)

Listorti: (4) Even though there are many factors not related to environmental causality, the relationships are strong enough to call it critical.

Ryan: (3) *There are a number of alternative factors other than environment that might lead to an increase or decrease Childhood Cancer Incidence and Mortality. Hence this indicator is not definitive for determining trends in underlying environmental conditions. However, many conditions can be attributed to environmental or occupational exposures so the indicator is quite useful.*

Walker: (3) The indicator is a numerical value whose trend over time may illuminate underlying trends in environmental conditions.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (1[mortality]/4[incidence])

Listorti: (4)

Ryan: (3)

Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)
Ryan: (4)
Walker: (3)

- e) The data are comparable across time and space, and representative¹¹ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (None)
Listorti: (4)
Ryan: (4)
Walker: (3)

- f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

Please Explain:

Goldman: See comment (1)

Listorti: Even though there are many factors not related to environmental causality, the relationships are strong enough to call it critical.

Ryan: *This indicator is sufficiently associated with environmental conditions to meet the criterion as outlined. The impact of genetic factors mitigates its utility in assessing environmental impact. The objectivity criteria are met.*

¹¹ An indicator seeks to describe trends in an overall target “population” (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

Walker: [no answer provided]

- 5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: If you *must* present the mortality data it should be secondary to the incidence data (rather than presenting it first, which makes it appear to be the more relevant indicator).

A graphic should provide separate data for the two most common cancer primary sites for children (leukemia and brain). There are not large ethnic and racial disparities in childhood cancer incidence and thus I am not recommending that you present a breakdown.

Listorti: Language could definitely be simplified to make it easier for the general public and policy makers to understand the problem. Also, need to make the point very clear in articles and reports outside the scientific/medical community that “children are not little adults” and respond to much lower exposures.

Ryan: *The overall trends presented are informative and useful. However, the presentation by EPA Region is less so and are quite difficult to follow in the presentation of Figure 092. The Mortality rates for each Region cross repeatedly and those with similar colors are difficult to follow. I would suggest a different presentation. However, the general trend is easily seen from the presentation and the variability across time and region is discernible. The national trend downward is evident as well. It would be interesting to examine the differences between Regions. Also, a state-by-state presentation would be informative. Figure 093 is clear and easy to follow. Some discussion of the variability from year to year vis a vis perhaps methodological differences in data collection may give more insight.*

Walker: [no answer provided]

- 6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: The introduction should stress more recent understandings that not just purely genetic or environmental factors are involved with childhood cancer but that gene/environment interactions appear to be involved (classically Ataxia Telengectasia Syndrome and UV light) but more recently (and subtly) for leukemia.[5] Also it should be mentioned that there are familial cancer syndromes involving multiple sites (e.g. Li-Fraumeni).

The introduction should talk about childhood cancer as an array of diagnoses probably with a number of different causal factors. It should give statistics for the proportions of cancers that most commonly occur (leukemia, brain, bone, lymphoma) and also discuss how childhood cancers are dissimilar from cancers in adults (more of the are of embryonic origin), justifying splitting them out as a separate category.

Listorti: Gaps exist in poor populations and children who die before cancer is diagnosed. Data may not adequately show causes of multiple sources or cumulative effects. Nor do they indicate importance of socioeconomic factors like diet/nutrition, access to medical care for early detection, etc.

Ryan: Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.

Walker: Site-specific cancer mortality should be the indicator. Cancers that arise in the pediatric population differ from those that occur among adult with respect to the distributions of anatomic sites of involvement.

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD with the modifications identified above.

Listorti: [no answer provided]

Ryan: X Should be included in ROE06 TD.

Walker: X Should be included in ROE06 TD with the modifications identified above.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **Childhood Asthma Prevalence & Mortality**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (1[mortality]/4[prev]) I am not sure why this one is set apart from the other asthma indicator. The two indicators could be combined as long as age groups are broken out. As with the earlier discussion, I think that the prevalence but not the mortality data are appropriate and useful. Trends in mortality for asthma have been largely shaped by improvements in treatment and that is not a reflection of the health of the environment.

Listorti: (4) Good indicator of overall health picture.

Ryan: (4) *Childhood Asthma Prevalence and Mortality is not likely to be a good indicator of overall health, but may an important indicator of the impact of environment on health as asthma attacks can be triggered by environmental insult. The data as reported are not,, however, specific to any environmental specific to an measured insult, and include specific genetic associatiosn and effects of non-environmental exposures, such as exercise. Further, more finely tuned statistics, including for example deaths whose causes may be inferred to be associated with environmental insult may prove more precise. Examples may include asthma attacks on days with high ozone or particulate, or in setting known for the presence of aeroallergens. There are some hypothesis extant that suggest that environmental exposure in utero or at a very young age may substantially alter the etiology and onset of asthma in children. Further, the time scale over which such exposures can be effective in producing such effects is short affording a better understanding of the link between the environment, genetics, and the etiology of this disease. While some characteristics associated Childhood Asthma Prevalence and Mortality with have strong environmental components, e.g., exposure of the developing fetus or embryo to certain others may not. This weakens the utility of the indicator.*

Walker: (3)

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the

other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (1[mortality]/4[prev]) See comment (1)

Listorti: (3) Good indicator, but many factors are not attributable to environment.

Ryan: (3) *The specific question to be addressed by these Group 1 indicators is “What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?” To the degree to which one believes that Childhood Asthma Prevalence and Mortality has an environmental association, then the indicator is of importance. Genetic factors also contribute as do the interaction of genetics with exposures experienced in utero. Hence the factor is of great importance, but may not be definitive. This precipitates my downgrading the rating from 4 to 3.*

Walker: (3) Indicator covers area of increasing importance environmentally, as more asthma triggers are identified and as the focus continues on the relevance of gene-environment interactions to the prevalence of asthma.

3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (1[mortality]/4[prev]) See comment (1)

Listorti: (4) Even though many factors are not associated with environment, there are enough strong relationships to say it fully meets the criteria.

Ryan: (3) *There are a number of alternative factors other than environment that might lead to an increase or decrease Childhood Asthma Prevalence and Mortality. Hence this indicator is not definitive for determining trends in underlying environmental conditions. However, many*

conditions can be attributed to environmental or occupational (to the parents) exposures so the indicator is quite useful.

Walker: (3) Indicator is a numerical value whose trend over time will draw attention to underlying environmental trends including exposure to both allergens and irritants early in life.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (1[mortality]/4[prev])

Listorti: (3)

Ryan: (3)

Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (3)

Listorti: (4)

Ryan: (4)

Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (3)

Listorti: (4)

Ryan: (4)

Walker: (3)

e) The data are comparable across time and space, and representative¹² of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (2)

Listorti: (4)

Ryan: (4)

Walker: (3)

f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

Please Explain:

Goldman: For mortality, see my comments above in (1). For prevalence, the data are based on self reports of physician diagnosed asthma so there is some element of recall involved. Also

¹² An indicator seeks to describe trends in an overall target "population" (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

there is some variability in diagnosis of asthma. In terms of comparisons across space and time it is of course relevant that the NHIS changed the asthma questions on its survey in 1997, however, the data have been collected consistently since that time.

Listorti: There has been a global increase in asthma, but the reasons are still not certain. Updates on causality would be helpful to see if the reasons for causality are now clearer. In addition, available data do not adequately reflect socioeconomic factors like poverty, poor housing, and indoor air pollution, which are environmentally based.

Ryan: *This indicator is sufficiently associated with environmental conditions to meet the criterion as outlined. The impact of genetic factors mitigates its utility in assessing environmental impact. The objectivity criteria are met.*

Walker: The indicator is derived from the best available data base, despite its limitations.

5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: The graphic for asthma mortality is not helpful; these are rare events and by breaking it down into regions a lot of the differences between regions are obscured. If you must report the mortality data (and I recommend not) then I would suggest something like a five-year moving average or perhaps taking it to a larger level such as the four PHS regions.

I suggest that race/ethnic trends for asthma prevalence be presented separately. There are large racial disparities, which are likely to have some relationship to differences in environmental conditions. Data should be presented for African Americans, and any other major race/ethnic groups for which there are valid data. Such data could be tabulated with perhaps a prevalence rate and 95% confidence intervals.

Listorti: When environmental factors are attributable, they should be highlighted in reports.

Ryan: *The overall trends presented are informative and useful. However, the presentation by EPA Region is less so and are quite difficult to follow in the presentation of Figure 094. The Mortality rates for each Region cross repeatedly and those with similar colors are difficult to follow. I would suggest a different presentation. However, the general trend is easily seen from the presentation and the variability across time and region is discernible. The national trend upward is evident as well. However the very large variability from year to year, especially in Region 7 may be having undue influence on the national trend. It would be interesting to examine the differences between Regions. Also, a state-by-state presentation would be informative. The data gap is not well explained. Figure 095 is clear and easy to follow.*

Walker: [no answer provided]

- 6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: The introduction should take note of air pollution as an environmental trigger!

It is important to note that there are great uncertainties in intercensal population estimates and these can impact conclusions about trends in prevalence and mortality data.

Additionally in very young children there is some inconsistency in the diagnosis of asthma (versus wheezing associated respiratory infections). This should be noted.

Listorti: Would be useful if data could pick up poverty aspects, which are considerable.

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

Walker: [no answer provided]

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD with the modifications identified above.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD.

Walker: X Should be included in ROE06 TD.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **Preterm Delivery**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (3) See earlier comments with regards to the overlap between this metric and the low birthweight indicator. Preterm birth is much more common among multiple births, and the prevalence of multiple births has increased in recent years due to the use of assisted reproductive technology. Also very young mothers and older mothers are more at risk and rates of birth to younger and older mothers change markedly over time. I think this would be a much more useful indicator if modified to focus on preterm singleton births to mothers between 18-39 y. of age. [1] [6] By limiting these data to singleton births to women 18-39 these data would be more *comparable across space and time*, a major criterion for this report.

Listorti: (2) Too many factors not attributable to environment

Ryan: (3) *Preterm Delivery may be a good indicator of overall health of the fetus and mother, but is not likely to be a good indicator of environmental effects due to the many competing mechanisms causally related to this effect, e.g., genetics, dietary choices, etc*

Walker: (3) Among preterm children, cognitive and neurologic impairment is common at school age. (Marlow et al, 2003) In summary, the association between risks of morbidity and mortality and preterm delivery is well documented at same time.

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (4)

Listorti: (2) Too many factors not attributable to environment

Ryan: (2) *The specific question to be addressed by these Group 1 indicators is “What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?” To the degree to which one believes that Preterm Delivery has an environmental association, then the indicator is of importance. Genetic factors also contribute as do the interaction of genetics with exposures experienced in utero. Hence the factor may be of importance, but may not be definitive.*

Walker: (2) Indicator covers an area of less importance environmentally. The literature identifies the important causes of preterm delivery as: genitourinary infection, multiple pregnancy, pregnancy-induced hypertension, and strenuous physical labor.

3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn’t meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (2) See comment (1)

Listorti: (2) Too many factors not attributable to environment

Ryan: (None) *There are a number of alternative factors other than environment that might lead to an increase or decrease Preterm Delivery. Hence this indicator is not definitive for determining trends in underlying environmental conditions. However, many conditions can be attributed to environmental or occupational (to the parents) exposures so the indicator is quite useful.*

Walker: (1) Indicator is a numerical value. The trend over time will not illuminate underlying environmental trends.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (2)

Ryan: (2)

Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)
Walker: (3)

- e) The data are comparable across time and space, and representative¹³ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

Please Explain:

Goldman: [no answer provided]

Listorti: Whereas the information overall is excellent, there are too many factors not attributable to environment for it to be useful.

Ryan: *This indicator is sufficiently associated with environmental conditions to meet the criterion as outlined. The impact of genetic factors mitigates its utility in assessing environmental impact. The objectivity criteria are met.*

Walker: The indicator is derived from the best available data bases despite its limitations.

¹³ An indicator seeks to describe trends in an overall target “population” (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

- 5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: See my comments under question (1) as to the desirability of focusing these data on singleton births to women 18-39. Additionally, I suggest that race/ethnic trends be presented separately. There are large racial disparities, which are likely to have some relationship to differences in environmental conditions. Data should be presented for African Americans, Asians, and American Indian/Alaskan Natives as well as for Hispanic versus non-Hispanic babies..

Also, why not include a map, to show state by state variation?

Listorti: [no answer provided]

Ryan: *The overall trends presented are informative and useful. However, the presentation by EPA Region is less so. I would suggest a different presentation. However, the general trend is easily seen from the presentation and the variability across time and region is discernible. The national trend upward is evident as well.*

Walker: [no answer provided]

- 6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: [no answer provided]

Listorti: [no answer provided]

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

Walker: [no answer provided]

- 7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD with the modifications identified above.

Listorti: X Should *not* be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD.

Walker: X Should *not* be included in ROE06 TD.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **Blood Lead Level**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (4)

Listorti: (4) Gives good overall health picture with many direct linkages to environment.

Ryan: (3) *Blood lead level in and of itself is unlikely to be a good indicator of general health. However, it may serve as a surrogate for other health-related factors ranging from housing stock to health care availability. Further, it may be a surrogate for other environmental exposures.*

Walker: (3) Indicator reflects exposure and disease (lead intoxication), and therefore, it is AA&U.

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (4)

Listorti: (4) Gives good overall health picture with many direct linkages to environment.

Ryan: (3) *The specific question to be addressed by these Group 1 indicators is "What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?" Blood lead levels have served to distinguish exposure groups in many contexts. City dwellers for*

instance, especially those in the older Northeastern cities, often display higher blood lead levels while those in more rural or newer areas are less likely to manifest high blood lead concentrations. Hence this indicator fulfils the criterion of interest.

Walker: (3) Biomonitoring data can be useful in understanding the extent to which people are exposed. The data cannot necessarily indicate whether such exposures are likely to induce disease. Biomonitoring strong suit is that it directly measures the amount in body fluid or tissue. Those exposure data are much more relevant for health risk assessment than are extrapolation from chemical concentrations in soil, air, or water.

3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (4)

Listorti: (4) Gives good overall health picture with many direct linkages to environment.

Ryan: (None) *Lead exposure comes from environmental contamination; there is not endogenously produced lead in the body. Blood lead concentrations are mitigated by genetic predisposition and similar exposures experienced by two different individuals may lead to different blood lead levels. Nevertheless, this is an important marker as effects are primary and can be measured at very low levels of this indicator. Long term trends are also of interest.*

Walker: (3) Indicator is a numerical value. The trend over time may illuminate underlying environmental trends (ie increase or decrease in exposure to lead and/or new sources of the metal).

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- e) The data are comparable across time and space, and representative¹⁴ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

Please Explain:

Goldman: [no answer provided]

Listorti: Gives good overall health picture with many direct linkages to environment.

Ryan: *This indicator is sufficiently associated with environmental conditions to meet the criterion as outlined. The impact of genetic factors only slightly mitigates its utility in assessing environmental impact.*

Walker: Indicator is derived from the best available data base despite its limitations.

- 5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

¹⁴ An indicator seeks to describe trends in an overall target "population" (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

Goldman: The presentation should show trend data over time (as for asthma).

Listorti: [no answer provided]

Ryan: *The overall trends presented are informative and useful. The Table (98-015) may be more effectively shown as a graph, however.*

Walker: [no answer provided]

- 6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: The introduction should discuss other possible sources of lead such as cultural practices (folk remedies, for example) and para-occupational exposures.

Listorti: A gap lies with the wide range of multiple sources besides leaded gasoline and lead-based paint, which have had the emphasis of research. The problem is with coverage, mainly in poor neighborhoods where need for reporting may be greatest, because general public and physicians are not fully aware of the problem which therefore can often go undiagnosed. Major limitation is with coverage of children at high risk and understanding of the wide variety of sources, from gasoline to flaking paint, to food, followed by occupational sources in the “informal sector.” Many tools are available but not necessarily used by the public health community and can be extremely useful in identifying potential high risk groups, e.g., gas stations which may still sell leaded gasoline, demographics of poor neighborhoods, especially immigrant communities (where food may be a source), literature reviews in the popular press to indicate potential public awareness, level of active community groups in poor neighborhoods, etc.

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

Walker: [no answer provided]

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD with the modifications identified above.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD.

Walker: X Should be included in ROE06 TD.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **Blood Mercury Level**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (3) Why are only data for women and babies included? There is ample evidence for mercury toxicity to adults as well as children, including males! [7, 8] The data should be presented in a manner similar to lead, if at all possible.

Listorti: (4) Gives good overall health picture with many direct linkages to environment.

Ryan: (3) *Blood Mercury Level in and of itself is unlikely to be a good indicator of general health. However, it may serve as a surrogate for other health-related factors including dietary patterns. Further, it may be a surrogate for other environmental exposures.*

Walker: (3) Measuring a particular chemical compound in the body for the first time does not mean that it is new to the human body or that the level is increasing. Although testing for a biomarker can take a short period (days) discerning its impact on health takes much longer (eg. years).

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (4)

Listorti: (4) Gives good overall health picture with many direct linkages to environment.

Ryan: (3) *The specific question to be addressed by these Group 1 indicators is “What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?” Blood Mercury Levels may serve to distinguish exposure groups in some contexts. Fish eaters, those near large lakes and rivers, and others often display higher blood mercury levels while those not consuming fish, for example, are less likely to manifest high blood mercury concentrations. Hence this indicator fulfils the criterion of interest.*

Walker: (3) Biomonitoring data can be useful in understanding the extent to which people are exposed. The data cannot necessarily indicate whether such exposures are likely to induce disease. Biomonitoring strong suit is that it directly measures the amount in body fluid or tissue. Those exposure data are much more relevant for health risk assessment than are extrapolation from chemical concentrations in soil, air, or water.

3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (4)

Listorti: (4) Gives good overall health picture with many direct linkages to environment.

Ryan: (None) *Mercury exposure comes from environmental contamination; there is not endogenously produced mercury in the body. It is not well known if Blood Mercury concentrations are mitigated by genetic predisposition thus affecting measured levels under similar exposures. Nevertheless, this is an important marker as effects are primary and can be measured at very low levels of this indicator. Long term trends are also of interest.*

Walker: (3) Indicator is a numerical value. The trend over time may illuminate underlying environmental trends.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (3)
Listorti: (4)
Ryan: (4)
Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- e) The data are comparable across time and space, and representative¹⁵ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

Please Explain:

Goldman: [no answer provided]

Listorti: Gives good overall health picture with many direct linkages to environment.

Ryan: *This indicator is sufficiently associated with environmental conditions to meet the criterion as outlined.*

Walker: Indicator is derived from the best available data base despite its limitations.

- 5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

¹⁵ An indicator seeks to describe trends in an overall target "population" (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

Goldman: See above. I would like to see data across the entire age span, for males as well as females, if such data are available.

Listorti: [no answer provided]

Ryan: *The overall trends presented are informative and useful. The Table (100-106) may be more effectively shown as a graph, however.*

Walker: [no answer provided]

- 6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: [no answer provided]

Listorti: [no answer provided]

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

Walker: [no answer provided]

- 7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD with the modifications identified above.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD.

Walker: X Should be included in ROE06 TD.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **Blood Cadmium Level**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (4)

Listorti: (3) Gives good overall health picture with many linkages to environment.

Ryan: (3) *Blood Cadmium levels in and of themselves is unlikely to be a good indicator of general health. However, it may serve as a surrogate for other health-related factors including dietary patterns and secondary exposure to environmental tobacco smoke. Further, it may be a surrogate for other environmental exposures.*

Walker: (3) Measuring a particular chemical compound in the body for the first time does not mean that it is new to the human body or that the level is increasing. Although testing for a biomarker can take a short period (days) discerning its impact on health takes much longer (eg. years).

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (4)

Listorti: (3) Gives good overall health picture with many linkages to environment.

Ryan: (3) *The specific question to be addressed by these Group 1 indicators is “What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?” Blood Cadmium levels may serve to distinguish exposure groups in some contexts. Occupationally exposed individuals, active smokers, and passive smokers often display higher blood cadmium levels while those not undertaking any of these activities are less likely to manifest high blood cadmium concentrations. Hence this indicator fulfils the criterion of interest.*

Walker: (3) Biomonitoring data can be useful in understanding the extent to which people are exposed. The data cannot necessarily indicate whether such exposures are likely to induce disease. Biomonitoring strong suit is that it directly measures the amount in body fluid or tissue. Those exposure data are much more relevant for health risk assessment than are extrapolation from chemical concentrations in soil, air, or water.

3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (4)

Listorti: (3) Gives good overall health picture with many linkages to environment.

Ryan: (None) *Cadmium exposure comes from environmental contamination; there is not endogenously produced cadmium in the body. It is not well known if Blood Cadmium concentrations are mitigated by genetic predisposition thus affecting measured levels under similar exposures. Nevertheless, this is an important marker as effects are primary and can be measured at very low levels of this indicator. Long term trends are also of interest.*

Walker: (3) Indicator is a numerical value. The trend over time may illuminate underlying environmental trends.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (3)
Ryan: (4)
Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (3)
Ryan: (4)
Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (3)
Ryan: (4)
Walker: (3)

- d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (3)
Ryan: (4)
Walker: (3)

- e) The data are comparable across time and space, and representative¹⁶ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (3)

Ryan: (4)

Walker: (3)

- f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (3)

Ryan: (4)

Walker: (3)

Please Explain:

Goldman: [no answer provided]

Listorti: Gives good overall health picture with many linkages to environment.

Ryan: *This indicator is sufficiently associated with environmental conditions to meet the criterion as outlined.*

Walker: Indicator is derived from the best available data base despite its limitations.

- 5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

¹⁶ An indicator seeks to describe trends in an overall target "population" (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

Goldman: [no answer provided]

Listorti: [no answer provided]

Ryan: *The overall trends presented are informative and useful. The Table (101-Cadmium) may be more effectively shown as a graph, however.*

Walker: [no answer provided]

- 6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: [no answer provided]

Listorti: [no answer provided]

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

Walker: [no answer provided]

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD.

Walker: X Should be included in ROE06 TD.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **Blood POPs Level**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (4) I don't think that the title "Blood POPs" is very informative. I think that "Blood persistent pesticides and chemicals" might be more informative.

Listorti: (4) Gives good overall health picture with many direct linkages to environment.

Ryan: (3) *Blood POPs levels in and of themselves is unlikely to be a good indicator of general health. However, it may serve as a surrogate for other health-related factors including dietary patterns. Further, it may be a surrogate for other environmental exposures.*

Walker: (3) The indicator can reflect either recent or current exposure s which may be related to adverse health effects (i.e., PCB mixtures produce changes in primary lymphatic organs,[bone marrow, etc] and in secondary lymphatic organs). The indicator is thus useful for evaluating human health and for contributing to the overall picture of human health. It should be noted that although the release of some POPs into the environment was substantially decreased during the last decade, their global occurrence has not ceased.

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (4)

Listorti: (4) Gives good overall health picture with many direct linkages to environment.

Ryan: (3) *The specific question to be addressed by these Group 1 indicators is “What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?” Blood POPs levels may serve to distinguish exposure groups in some contexts. Occupationally exposed individuals, those eating large amounts of foods containing POPs, and those with higher levels of body fat may display higher blood POPs levels while those not undertaking any of these activities are less likely to manifest high blood POPs concentrations unless their local area is contaminated. Hence this indicator fulfils the criterion of interest.*

Walker: (3) This indicator is of importance in addressing questions regarding trends in human health and in environmentally related disorders. While the results to date are mixed, studies suggest that organ chlorine pesticides may contribute to an increased risk of non-Hodgkin’s lymphoma (NHL). One study (Hardwell, et al) found NHL risk to be associated with serum chlordane and related compounds. Later studies have not found such evidence. IARC has found sufficient evidence for carcinogenicity of chlordane/ heptachlor.

3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn’t meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (4)

Listorti: (4) Gives good overall health picture with many direct linkages to environment.

Ryan: (3) *POPs exposure comes from environmental contamination; there is not endogenously produced POPs m in the body. It is not well known if Blood POPs concentrations are mitigated by genetic predisposition thus affecting measured levels under similar exposures. Nevertheless, this is an important marker as effects are primary and can be measured at very low levels of this indicator. Long term trends are also of interest.*

Walker: (3) The indicator is a numerical value whose trend over time may illuminate underlying trends in environmental condition. Parenthetically, it should be noted that the indicator may provide little information about the combined health effects of mixtures of compounds in blood. But organophosphates pesticides are an exception. There are several organophosphates that break down to ethyl metabolites. Each of these metabolites track combined exposure to several organophosphates. All the organophosphates act through common pathways in the body, so if they have an effect, it is, in fact the effect of a mixture.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- e) The data are comparable across time and space, and representative¹⁷ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

- f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

Please Explain:

Goldman: [no answer provided]

Listorti: Gives good overall health picture with many direct linkages to environment.

Ryan: *This indicator is sufficiently associated with environmental conditions to meet the criterion as outlined.*

¹⁷ An indicator seeks to describe trends in an overall target “population” (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

Walker: [no answer provided]

- 5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: [no answer provided]

Listorti: [no answer provided]

Ryan: *The overall trends presented are informative and useful. The Table 336-Organochlorine) may be more effectively shown as a graph, however. Further, temporal trends, where available, would be of interest.*

Walker: [no answer provided]

- 6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: Somewhere you should describe *why* you have lipid adjusted these data and *how* you did so. (Give the formula that you used.)

Rather than use the term “pesticide” everywhere the type of pesticide should be described for each chemical, e.g., chlordane, heptachlor, DDT, & mirex = insecticides; hexachlorobenzene = fungicide (not a pesticide and also a fungicide; a fungicide is a type of pesticide). HCB also has been used as an industrial antimicrobial and in the manufacture of other chemicals.

Listorti: The report does not mention whether pesticide *sales* are followed. Sales information could be useful to determine trends that could help compensate for the inadequacy of data collection, e.g., industrial consumption, home use, gardening, household pest control, urban/rural, etc. Presumably such information is available to pesticide manufacturers as part of their overall market analysis. This could help identify groups at risk who could then be targeted for prevention.

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

Walker: [no answer provided]

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD.

Walker: X Should be included in ROE06 TD.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **Urinary Pesticide/Herbicide Level**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (4) This indicator is oddly named. An herbicide is a category of “pesticide”. It would be accurate to say “Urinary Pesticide Levels”. For the organophosphates can the EPA utilize new measures developed by CDC that are informative about individual insecticide exposure levels?

Listorti: (4) Gives good overall health picture with many direct linkages to environment.

Ryan: (3) *Urinary Pesticide/Herbicide Levels in and of themselves is unlikely to be a good indicator of general health. However, it may serve as a surrogate for other health-related factors including dietary patterns. Further, it may be a surrogate for other environmental exposures.*

The markers chosen have several problems. 1-Naphthol, for example, is not a unique biomarker for carbaryl; it also can represent exposure to naphthalene. The dialkyl phosphates are general exposure markers for OPs, and are not specific to an individual OP.

Walker: (3) Measuring a particular chemical compound in the body for the first time does not mean that it is new to the human body or that the level is increasing. Although testing for a biomarker can take a short period (days) discerning its impact on health takes much longer (eg. years).

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (4)

Listorti: (4) Gives good overall health picture with many direct linkages to environment.

Ryan: (3) *The specific question to be addressed by these Group 1 indicators is “What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?” Urinary Pesticide/Herbicide Levels may serve to distinguish exposure groups in some contexts. However, the lack of persistence of these compounds in the body makes extrapolation to exposure difficult; often values are <LOD although high exposures, and hence effects, may have occurred only a few weeks ago. Because of this, the utility of such markers is limited. They are important, however, in cases for which exposure can be established.*

Walker: (3) Biomonitoring data can be useful in understanding the extent to which people are exposed. The data cannot necessarily indicate whether such exposures are likely to induce disease. Biomonitoring strong suit is that it directly measures the amount in body fluid or tissue. Those exposure data are much more relevant for health risk assessment than are extrapolation from chemical concentrations in soil, air, or water.

3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (4)

Listorti: (4) Gives good overall health picture with many direct linkages to environment.

Ryan: (3) *Urinary Pesticide/Herbicide exposure comes from environmental contamination; there is not endogenously produced Urinary Pesticide/Herbicide metabolites in the body. It is not well known if Urinary Pesticide/Herbicide metabolite concentrations are mitigated by genetic predisposition thus affecting measured levels under similar exposures, although there is*

some data suggestion different expressions of CYP pathways may results in differential rates of metabolism for some of these compounds. Further, the new data on pyrethroids is not yet in this report. Nevertheless, this is an important marker as effects are primary and can be measured at very low levels of this indicator. Long term trends are also of interest.

Walker: (3) Indicator is a numerical value. The trend over time may illuminate underlying environmental trends.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)

Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (4)
Walker: (3)

d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

e) The data are comparable across time and space, and representative¹⁸ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (4)
Walker: (3)

Please Explain:

¹⁸ An indicator seeks to describe trends in an overall target “population” (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

Goldman: [no answer provided]

Listorti: Gives good overall health picture with many direct linkages to environment.

Ryan: *This indicator is sufficiently associated with environmental conditions to meet the criterion as outlined.*

Walker: Indicator is derived from the best available data base despite its limitations.

5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: I think that the creatinine adjusted data are more relevant and that is not necessary to present the raw data as well. In any case EPA should explain why the creatinine adjustment was done and how its interpretation is different.

Listorti: [no answer provided]

Ryan: *The data presentation here is not sufficient. Most of the data are below LOD because of the factors discussed above.*

Walker: [no answer provided]

6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: As noted above, herbicides are pesticides. Rather than use the term pesticide everywhere, I recommend using that term only when you refer to the entire class. Otherwise, carbamates, organophosphates, and pyrethroids=insecticides; and 2,4,5-T, 2,4-D and atrazine=herbicides.

Listorti: The report does not mention whether pesticide *sales* are followed. Sales information could be useful to determine trends that could help compensate for the inadequacy of data collection, e.g., industrial consumption, home use, gardening, household pest control, urban/rural, etc. Presumably such information is available to pesticide manufacturers as part of their overall market analysis. This could help identify groups at risk who could then be targeted for prevention.

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the*

sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.

Walker: [no answer provided]

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD with the modifications identified above.

Walker: X Should be included in ROE06 TD.

Attachment 2: Comment Sheet for Group 1 Indicators

Topic Area: **Human Health**
Indicator Name: **Phthalate Exposure**

- 1) Please indicate the extent to which you think the proposed indicator is appropriate, adequate, and useful (AA&U) for evaluating human health and for contributing to an overall picture of human health.

1	2	3	4
Indicator is not AA&U	Indicator is of somewhat AA&U	Indicator is largely AA&U	Indicator is completely AA&U

Goldman: (4) I think it would be more accurate and more consistent with the other biomonitoring indicators to call this indicator "Urine phthalate metabolites"

Listorti: (2) In principle the sources for phthalates make it quite appropriate, but the known health effect have been poorly studied and make it hard to use the data.

Ryan: (3) *Phthalates represent an important class of compounds that is now ubiquitous in our environment. However, measurement of Phthalate Exposures in and of themselves is unlikely to be a good indicator of general health. However, it may serve as a surrogate for other health-related factors including dietary patterns, and use of plastic materials. Further, it may be a surrogate for other environmental exposures.*

Some of the markers chosen are problematic. For example, mono-cyclohexyl phthalate was below LOD for at least 90% of the samples. Mono-n-octyl phthalate was only slightly better.

Walker: (3) Measuring a particular chemical compound in the body for the first time does not mean that it is new to the human body or that the level is increasing. Although testing for a biomarker can take a short period (days) discerning its impact on health takes much longer (eg. years).

- 2) Please indicate the extent to which you think the proposed indicator makes an important contribution to answering the specific ROE question it is intended to answer (see Attachment 1 for list of questions). (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators, or if it covers an area of less or diminishing importance environmentally.)

1	2	3	4
Indicator is not important	Indicator is of minor importance	Indicator is important	Indicator is critical

Goldman: (4)

Listorti: (None) Important because it keeps a pulse on many factors with high potential to adverse effect human health, viz., food packaging, ubiquitous plastics, detergents, personal care products, etc.

Ryan: (3) *The specific question to be addressed by these Group 1 indicators is “What are the trends in human disease and conditions for which environmental pollutants are thought to be to[sic] risk factors including across population subgroups and geographic regions?” Phthalate Exposure Levels may serve to distinguish exposure groups in some contexts. However, the persistence of these compounds in the body makes pinpointing the time of exposure very difficult. Because of this, the utility of such markers is limited. They are important, however, in cases for which exposure can be established.*

Walker: (3) Biomonitoring data can be useful in understanding the extent to which people are exposed. The data cannot necessarily indicate whether such exposures are likely to induce disease. Biomonitoring strong suit is that it directly measures the amount in body fluid or tissue. Those exposure data are much more relevant for health risk assessment than are extrapolation from chemical concentrations in soil, air, or water.

3) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1
Doesn't meet
the definition

2
Only partly
meets the definition

3
Largely meets
the definition

4
Fully meets
the definition

Goldman: (4)

Listorti: (2) In principle the sources for phthalates make it quite appropriate, but the known health effect have been poorly studied and make it hard to use the data and the actual levels of measurement are not widespread.

Ryan: (3) *Phthalate Exposure comes from environmental contamination; there is not endogenously produced phthalates in the body. It is not well known if such concentrations are mitigated by genetic predisposition thus affecting measured levels under similar exposure. Nevertheless, this is an important marker. Long term trends are also of interest.*

Walker: (3) Indicator is a numerical value. The trend over time may illuminate underlying environmental trends.

4) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (2)

Ryan: (4)

Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (2)

Ryan: (4)

Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (2)

Ryan: (4)

Walker: (3)

- d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (2)

Ryan: (4)

Walker: (3)

- e) The data are comparable across time and space, and representative¹⁹ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (2)

Ryan: (4)

Walker: (3)

- f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (2)

Ryan: (4)

Walker: (3)

Please Explain:

Goldman: [no answer provided]

¹⁹ An indicator seeks to describe trends in an overall target "population" (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

Listorti: In principle the sources for phthalates make it quite appropriate, but the known health effect have been poorly studied and make it hard to use the data and the actual levels of measurement are not widespread.

Ryan: *This indicator is sufficiently associated with environmental conditions to meet the criterion as outlined.*

Walker: Indicator is derived from the best available data base despite its limitations.

5) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: Given the importance of these chemicals as potential reproductive toxicants it would be important to give levels of exposure for women and men of childbearing age as well as for the general population. A presentation like the lead presentation (that gives a more extensive breakdown by age, gender and race) would be preferable.

Listorti: [no answer provided]

Ryan: *The data presentation here is not sufficient. Some of the data are below LOD because of the factors discussed above. Pie charts of total phthalate exposure may offer an alternative.*

Walker: [no answer provided]

6) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 5. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: I am surprised that the introduction does not acknowledge the potential endocrine and developmental effects of these compounds and the National Toxicology Program Center for the Evaluation of Risks to Human Reproduction reviews.[9-15] These should be referenced.

Listorti: Phthalate exposure deserves more attention to get a better grasp on its short and long term health effects, as well as improved monitoring. The products which contain phthalates are ubiquitous and it should be measured better.

Ryan: *Any such indicator is potentially limited due to data quality. While I am sure that every effort has been taken to ensure the adequacy of the measure, there are still likely to be missing data problems, imputation problems, etc., the limit the precision of the estimate. However, the sample size of the raw data and the description of imputation and other methods lead one to believe that this is an excellent single statistic to use in estimating health impacts.*

Walker: [no answer provided]

7) Overall, this indicator:

Goldman: X Should be included in ROE06 TD.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD with the modifications identified above.

Walker: X Should be included in ROE06 TD.

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General Questions for Group 1 Indicators

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Attachment 3: Comment Sheet for General Questions for Group 1 Indicators

Topic Area: **Human Health**

- 1) Considering the Group 1 indicators *collectively*, do any of these indicators clearly seem to be more appropriate, adequate, or useful for evaluating human health and/or for contributing to an overall picture of human health than others? Do any seem to be more important than the others for answering the question(s) they are intended to answer? (Note: An indicator may be judged less important if it makes a smaller or less critical contribution to answering the question posed than the other indicators or if it covers an area of diminishing interest environmentally.)

Goldman: I think that they are all important, and critical. That being said, I have a number of suggestions for paring down or refocusing certain of the indicators where both mortality and incidence or prevalence data are available. Incidence or prevalence data are the best measures of “changes in human health or ecological condition” particularly for disease entities, such as asthma and childhood cancer, where the quality of, and access to medical care play a major role in mortality. In other words, the mortality data violate the criterion that the *data are comparable across time and space* since treatment for many diseases has improved drastically over time and because there is variability in access and quality of medical care across various regions of the country. So, I would strongly recommend that cancer be pared down to “cancer incidence”; asthma to “asthma prevalence”, birth defects to “birth defects prevalence” (NOT incidence), childhood cancer to “childhood cancer incidence” and childhood asthma to “childhood asthma prevalence”. If EPA *must* include the mortality statistics as well, then the report should lead with the incidence and prevalence data and not with the mortality data, which are quite misleading.

Listorti:

- Imbalance in group of indicators: some categories seem subjected to overkill, with duplicate or highly similar lists, e.g., infants and mortality (infant mortality, low birthweight, birth defects, preterm delivery) where environmental links are tenuous, whereas other indicators are very sparse, e.g. infectious gastrointestinal & arthropod-borne, where they are important and on the increase.
- Extremely useful: cancer incidence and mortality, asthma prevalence and mortality, COPD mortality, Infectious gastrointestinal and arthropod-borne disease prevalence, childhood cancer incidence and mortality, childhood asthma prevalence and mortality, blood lead level, blood mercury level, blood cadmium level, blood POPs level, urinary pesticide/herbicide level, phthalate exposure,

- Questionable utility: the others on the list are of questionable use because the links to environment are tenuous, given the high number of contravening variables. They should be maintained but the reports should be clear how they may or may not reflect environmental causalities.
- ***Create four categories for analyses of indicators: The wildlife community⁺ and International Panel on Climate Change (IPCC) have both repackaged key information into four categories that facilitate decision making in the absence of statistically significant data. The categories are, roughly:
 - i) what we know and can prove with statistical significance,
 - ii) what we know but cannot prove with statistical significance,
 - iii) what we don't fully understand, but our professional judgment tells us is important,
 - iv) what we don't know and understand.

This can help get the message out to the general public as well as help public officials with out health or environmental backgrounds make sensible decisions.⁺⁺

Ryan: *Several of the indicators are of general utility in evaluating the overall health of the nation, but offer little insight into the specific impact of the environmental on health. I have indicated these in my write-ups. Further, a few of the indicators offer insight only into very small populations either geographically or in terms of number of those potentially exposed. While this limits the overall utility of the indicator, it does not necessarily make of less importance. Some diseases, especially environmentally associated diseases may not be widespread geographically or in terms of numbers of individuals. However, the effects on those individuals may be devastating. An example is mercury exposure and Minamata Disease. My comments address these specifically and I won't repeat those comments here.*

Walker: Less important indicators include 1) General mortality or crude death rate; 2) Life expectancy; 3) Preterm delivery or Preterm birth; 4) Arthropod-borne disease prevalence

- 2) Are there any additional *national-level* indicators that make an important contribution to answering one of the ROE questions in your topic area, but were not proposed for ROE06, that you would recommend? (Proposed indicators should meet the ROE indicator definition and criteria, be national in scale, be of a quality that likely would pass this type of peer review, and have data that are readily available. For any new indicators

⁺ see i) *Our Stolen Future*, Theo Colborn, *et. al.*, 1997, Annexes, and ii) WMO/UNEP, Report of the International on Climate Change, Second Assessment, 1995.

⁺⁺ For example, in a African city with high malaria levels, malariologists could not agree on technical information and did not issue a report that contained remedial measures. That technical information (pH levels for breeding and flight ranges) would not have made a difference to the implementation of a city wide program to keep storm drains clean which was not implemented.

proposed, provide justification for their inclusion and list references or citations for the associated underlying data sources.)

As you consider this question, ***please read Attachment 5***, which provides the list of human health and other indicators presented in ROE03 that EPA does not intend to carry forward to ROE06, along with EPA's rationale for withdrawing them. If you disagree with EPA's rationale and feel any of these indicators should be included in ROE06, please so indicate in your response to this question, along with your rationale for why they should be included. Note: The full text and graphics for the ROE03 indicators can be viewed on-line at: <http://www.epa.gov/indicators/roe/html/tsd/tsdHealth.htm>

Goldman: I do have comments with regards to some of the decisions, and/or rationale for decisions, as presented in Attachment 5 as described below.

1) Production of ozone depleting substances - C

This variable is deleted for various stated reasons: lack of comparability of reporting among various countries; lack of data on imports; and lack of a clear temporal relationship between production of ODCs and release into the environment. First, since this is a report about US environmental performance why not, then, focus on reporting on production by the US as an important indicator of performance? Further, the half-life of damage from ODCs released to the environment is so long that there is not an immediate temporal association and it is not at all a stretch to assume that companies will be successful in marketing ODC products that are produced and that customers, eventually will utilize them in uses that over time will result in environmental releases. Despite deficiencies in the international data, this is a critically important issue and I would recommend that the EPA report these data and, if needed work to improve the data over time rather than dropping this indicator.

2) Number of people living in counties with ambient air concentrations above the NAAQS-C

This is a very important indicator of health and should not be dropped. I suggest that, rather than drop these data, to either assess trends of past exposure using the newer NAAQS or for future data to continue to report the "old" NAAQS along with the new ones. It is stated that this is "not a valid exposure indicator because it is not based on measurement of an actual marker of exposure measured on individuals". However, measurements of ambient air concentrations of pollutants are valid exposure indicators and should be retained in this report, since there is, at this point in time, no valid individual level biomarker that can be utilized instead and also because this indicator is so useful for environmental management.

3) Percent of population living in homes where someone smokes regularly inside the home-D

The justification for dropping this variable is that it "violates the ROE indicator definition, requiring that indicators be based on actual measurements and blood cotinine (sic) provides a

better indicator of children's exposure to smoke". The first part of this statement is not true. Numerous of the variables that are included in the report (notably, asthma prevalence) are derived from the same survey that was used for assessing the population living in homes where someone smokes regularly. Moreover, data derived from such surveys *are measurements*. Although blood cotinine measurements certainly give an assessment of the distribution of cotinine exposures in the population they do not tell you anything about the living conditions that are associated with such exposures. Data about smokers in the home helps track an important aspect of the *condition of the environment* that is not captured with the blood cotinine level. Therefore, both indicators are important and should be included in this report.

4) Beach days open –D and Waters with fish consumption advisories - D

Rather than drop these indicators the EPA could work with the states who are delegated to run these programs to obtain consistent data on water quality and fish contamination.

5) Radioactive waste and disposal - C

This is dropped because the DOE no longer makes the data publicly available post 9/11. Although it is easy to see why such data for individual locations may constitute a national security issue, surely the DOE could produce aggregate measures on production and inventory so that this very important issue can be tracked in the ROE. Whether these wastes are generated by production or cleanup is certainly an issue for managing them, however, this is an excellent Level 3 indicator.

6) Cardiovascular disease prevalence -C

The write-up indicates that this is dropped because "currently no national trend data are available on cardiovascular disease prevalence." This simply is not the case. Potential data sources include: National Health Interview Survey (prevalence of physician-diagnosed coronary heart disease, hypertension and stroke); National Hospital Discharge Survey (hospitalizations for cardiovascular disease); and National Health and Nutrition Examination Survey (hypertension).

7) Blood VOC; urinary arsenic; and chemical contamination

These seem to be important indicators and I agree with the justification for dropping the measures that were used in the ROE03 report. Is the EPA working with the other agencies (CDC in the case of the first two and the USGS for the third) to obtain more consistent national data to serve as indicators in these areas?

Listorti:

1. Housing Starts: I would propose adding "housing starts" to the list. They are readily available and reported on the national news regularly. They have a number of negative environmental consequences with health repercussions that are neglected:

- a) loss of productive arable land turned into housing developments which contribute to overall environmental degradation. For example, soil runoff, which pollutes local waterways as well as lakes, bays and the oceans. Locally, the Chesapeake Bay has been the subject of many analyses for pollution of the watershed, such as threats to oyster health, disease of fish in local waterways, etc.
- b) increase in of pesticides, mainly lawn care, which pollutes local waterways as well as lakes, bays and the oceans.
- c) excessive energy consumption from modern houses that contributes to global warming. Even though the housing industry can argue that they are more energy efficient than they were, the overall size of many new houses begs the issue.

The effects would require interpretation because they are not readily obvious to those not trained in environment or health. These consequences could be written up in 6 weeks.

2. *Urban Renewal programs.* I don't know how these are measured, but if data are available, they would be a good compliment to housing starts. Primarily because the overall environmental effects are largely positive.

3. *Poverty Index:* Overall the indicators do not reflect the effects of poverty of poor health or environmental exposures as compared with, for example, attention to minorities. They are directly linked, for example poor housing can be linked to respiratory disease.

The gist of these comments deals with trying to interpret existing data which EPA considers unreliable or not nationwide. With all due respect to EPA and statisticians, we need to be careful not to make good data the enemy of perfect data, which seems to be taking place.

-*Number of people living in Counties with Ambient Air Concentration above the NAQs:* Indicator is being withdrawn because it is considered unreliable because of population movements and changing air quality standards. Would it not be possible to get a measure of population movements and adapt the data? I follow the reasoning for accuracy, but it is hard to believe that more than 20% of a given population moves away, leaving 80% still adversely effected. If there is another indicator available which reflects the same risks, the consequences of dropping it are less extreme.

- *Chemical contaminants of streams and groundwater:* The indicator is being dropped because sampling techniques are not comparable. Would it be possible to see the overall percentage of bodies of groundwater where they are comparable? If everything which is not reportable nationwide is excluded, we loose a lot of information valuable to local populations whose numbers are undoubtedly significant even though not national.

- *Animal deaths and deformities:* The indicator is being dropped because trends are available only for waterfowl and reporting is voluntary. Would it not be possible to keep

the indicator and find out if waterfowl could serve as a sentinel species before it is dropped altogether?

Ryan: Number of People Living in Counties with Ambient Air Concentrations above the NAAQS. *This is still an important indicator of national air quality/health relationships and should be included.*

Walker: No additional indicators are recommended. A small number of indicators, that is relatively precise in terms environmental relevance would be highly productive.

Concerning data sources in quality for which questions were posed for each indicator, we make the following comment:

They are the best available. Most data sets are neither complete nor completely accurate. Each has problem and issues related to completeness, accuracy and timeliness Even the data set often considered most complete -- births and death records --includes some data elements that are underreported or inaccurately recorded congenital anomalies of newborn infants. Death records suffer from variability in determining cause of death and, specifically, in identifying true underlying causes, such as tobacco or alcohol.

Comments for Group 2 Indicators

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Attachment 4: Comment Sheet for Group 2 Indicators

Topic Area: **Air**
Indicator Name: **Blood Cotinine Level**

1) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (4)

Listorti: (4) Good indicator of smoking risks and identification of populations at risk.

Ryan: (4) *Blood Cotinine Level is an important indicator of exposure to an environmentally relevant contaminant. Measurement of this indicator can classify individuals into risk categories that insurance actuaries have found useful in assessing mortality trends. It meets the indicator definition supplied.*

Walker: (3) The indicator is a numerical value (nanogram per ml) whose trends over time may draw attention to underlying conditions of the environment. At present the most sensitive and specific marker for tobacco smoke exposure are nicotine and its metabolite, cotinine. Neither nicotine nor cotinine is usually present in body fluids in the absence of exposure to tobacco smoke, although unusually large intakes of some foods may produce measurable levels of nicotine and cotinine (Idle, 1990). Cotinine has a half-life in the blood or plasma of active smokers that ranges from less than 10 hr to approximately 40 hours; hence cotinine levels provide information about more chronic exposure to tobacco smoke in both active and involuntary smokers. Levels of cotinine can be used to gauge the intensity of exposure, and, thus, potential health risks.

2) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (3)
Walker: (3)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (3)
Walker: (3)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (3)
Ryan: (3)
Walker: (3)

- d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (4)
Ryan: (3)
Walker: (3)

- e) The data are comparable across time and space, and representative²⁰ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (3)

Ryan: (3)

Walker: (3)

- f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (3)

Walker: (3)

Please explain:

Goldman: [no answer provided]

Listorti: This is an excellent indicator of smoking trends.

Ryan: *All of these criteria are mitigated by the collection methodology and small sample size of the measured individuals.*

Walker: The indicator is derived from the best available data base, despite its limitations.

- 3) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

²⁰ An indicator seeks to describe trends in an overall target “population” (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

Goldman: In other publications from the CDC I have seen trend data for blood cotinine levels; I would suggest that such trends be included in the ROE if possible.

Listorti: Simplicity is the essence of getting the information out to groups that do prevention. The material provided for this report is too complicated for the general public, especially the three high risk groups cited, viz., non-smoking males, people under 20 and non-Hispanic African Americans. EPA should make sure that the right groups are targeted and have available simple, graphic information that they can use for prevention.

Ryan: *Alternative presentations might include pie charts and any trends expressed graphically.*

Walker: [no answer provided]

- 4) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 3. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: [no answer provided]

Listorti: It isn't clear what the sources are for environmental tobacco smoke (ETS) in non-smoking populations. This would be helpful in prevention. In addition, anti-smoking campaigns rarely stress the other health effects associated with smoking of second-hand smoke, e.g., asthma, and respiratory tract infections, especially among children. This could be a powerful tool in helping adults quit.

Ryan: *None.*

Walker: Although biological markers have provided importance evidence of population exposures, the utility of cotinine as an indicator of individual exposure has been questioned. Idle (1990) has reviewed the complex metabolism of nicotine and the many factors affecting the relationship between exposure to atmospheric nicotine and the concentration of cotinine in body fluids. He cautions against using any single determination of cotinine as a measure of exposure.

- 5) Overall, this indicator:

Goldman: X Should be included in ROE06 TD.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD.

Walker: X Should be included in ROE06 TD.

Attachment 4: Comment Sheet for Group 2 Indicators

Topic Area: **Land**
Indicator Name: **Pesticide Poisonings**

- 1) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (3)

Listorti: (2) The basic sources for the data are reported cases of poisonings that require medical attention, but do not necessarily allow for adequate analysis because they are considered confidential medical information.

Ryan: (2) *Pesticide Poisonings does not represent an especially useful measure of ambient condition, exposure, human health or ecological condition. It is more a measure of misuse, abuse, or uncontrolled availability of these compounds. Therefore, I cannot see how it meets the given criterion. It is an important measure from a regulatory point of view, but not from a national health and exposure point of view. Other measures such as soil levels or urinary biomarker levels offer a more useful indicator.*

Walker: (2) The indicator is derived from a “weak”, incomplete, bias data base and its trend over time may not draw attention to underlying condition of the environment. Under reporting of pesticide poisoning, even in locations where reporting is mandatory, is a significant problem. A significant drop in reports of pesticide-related illness has occurred in the past 10 years. While some of this change may be related to reporting patterns, some is undoubtedly due to the elimination of several very toxic pesticides, such as phosdrin, and ethyl parathion. Unfortunately, no single surveillance system tracks pesticide poisoning in the U.S. Several states have reporting systems.

- 2) To what extent do you think the indicator meets each of the following indicator criteria:
- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (3)

Listorti: (2)

Ryan: (1)

Walker: (2)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (3)

Ryan: (3)

Walker: (2)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (2)

Listorti: (2)

Ryan: (3)

Walker: (2)

- d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (3)

Walker: (2)

- e) The data are comparable across time and space, and representative²¹ of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (2)

Ryan: (3)

Walker: (2)

- f) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)

Listorti: (4)

Ryan: (3)

Walker: (2)

Please explain:

Goldman: There are some weaknesses in that there is not a complete count of call cases (because there is not complete reporting to poison centers nor is there systematic follow-up) but this is probably a good indicator of trends over time nonetheless.

Listorti: However interesting and accurate, the information is inadequate because it underreports the overall trends and is subject to misclassification.

Ryan: *All of these criteria are mitigated by the collection methodology and small sample size of the measured individuals.*

Walker: [no answer provided]

- 3) Do you have any suggestions for more effective graphic presentation of the data?

²¹ An indicator seeks to describe trends in an overall target "population" (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

If yes, please describe.

Goldman: I would like to see a breakout of data for children (but I recognize that the AAPCC does not provide a detailed breakout of data for children).

I like the use of three year averages.

Listorti: Figure 276-1 "Average Annual Pesticide Poisonings..." is interesting and informative⁴, by way too complicated. Too many variables to have an impact. Maybe just present one or two years showing the breakdown by rodenticides, fungicides, etc. in separate columns.

Ryan: *The presentation is quite clear with both trends and partitioning well presented.*

Walker: [no answer provided]

- 4) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 3. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: [no answer provided]

Listorti: The report does not mention whether pesticide *sales* are followed. Sales information could be useful to determine trends that could help compensate for the inadequacy of data collection, e.g., industrial consumption, home use, gardening, household pest control, urban/rural, etc. Presumably such information is available to pesticide manufacturers as part of their overall market analysis. This could help identify groups at risk who could then be targeted for prevention.

Nor does the report cite industrial type accidents, which are also available.

Ryan: *None.*

Walker: [no answer provided]

- 5) Overall, this indicator:

Goldman: X Should be included in ROE06 TD.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should *not* be included in ROE06 TD.

Walker: X Should *not* be included in ROE06 TD.

Attachment 4: Comment Sheet for Group 2 Indicators

Topic Area: **Land**

Indicator Name: **Human Exposure Under Control on Contaminated Lands**

- 1) To what extent do you think the indicator meets the following indicator definition:

An “indicator” is a numerical value derived from actual measurements of a pressure, ambient condition, exposure, or human health or ecological condition over a specified geographic domain, whose trends over time represent or draw attention to underlying trends in the condition of the environment.

1	2	3	4
Doesn't meet the definition	Only partly meets the definition	Largely meets the definition	Fully meets the definition

Goldman: (3) It isn't clear how “under control” is defined nor how these sites are monitored to assure that once the exposures are under control, they stay that way.

Listorti: (2) The report was unclear in describing overall exposures to sites not under the rubric of the Super Fund or the RCRA Corrective Action Program, e.g. municipal waste sites or on-site industrial disposal. Nor does it describe occupational exposures.

Ryan: (3) *This is an important indicator associated with environmental cleanup and corrective action associated with RCRA. Given the large number of individuals living close to contaminated lands, the magnitude of the exposure warrants measurement. This simple indicator offers a good surrogate for effectiveness of these programs*

Walker: (1) The limitations of this indicator clearly suggest that it does not meet the definition. For example, the indicator does not typically make measurement of exposure biomarkers among potentially exposed individuals. Actual exposure, as indicated by biomarkers, and which may be influenced by an individuals activity, is an important factor in evaluating human exposure to contaminated land

- 2) To what extent do you think the indicator meets each of the following indicator criteria:

- a) The indicator makes an important contribution to answering a question for the ROE. (In this context, “important” means that the indicator answers a substantial portion of and/or a critical part of the question.)

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (2)
Ryan: (4)
Walker: (1)

- b) The indicator is objective. It is developed and presented in an accurate, clear, complete, and unbiased manner.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (2)
Listorti: (2)
Ryan: (4)
Walker: (1)

- c) The underlying data are characterized by sound collection methodologies, data management systems that protect its integrity, and quality assurance procedures.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (3)
Listorti: (3)
Ryan: (4)
Walker: (1)

- d) Data are available to describe changes or trends, and the latest available data are timely.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (4)
Listorti: (3)
Ryan: (4)
Walker: (1)

- e) The data are comparable across time and space, and representative²² of the target population. Trends depicted in this indicator accurately represent the underlying trends in the target population.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (3)

Listorti: (2)

Ryan: (4)

Walker: (1)

- l) The indicator is transparent and reproducible. The specific data used and the specific assumptions, analytic methods, and statistical procedures employed are clearly stated.

1	2	3	4
Doesn't meet this criterion at all	Only partly meets this criterion	Largely meets this criterion	Fully meets this criterion

Goldman: (3)

Listorti: (4)

Ryan: (4)

Walker: (1)

Please explain:

Goldman: These questions are difficult to address, given the information that was provided to us about this indicator.

Listorti: However accurate and useful the data are for the selected sites, they do not give an indication of actual and potential risks for the population at large. About 40 million people live within 2.5 miles of a National Priority (NPL) site. Nor does it describe actual or potential exposures to the myriad of smaller municipal sites which may be considerable and are less likely to be operated under conditions

Ryan: *All of these criteria are met.*

Walker: The indicator is derived from the best available data base, despite its limitations.

²² An indicator seeks to describe trends in an overall target "population" (e.g., land area, type of surface water, type of emissions, U.S. population), yet data often can only be sampled from a subset of this population. The validity of the trends described by the indicator will depend on the degree to which the sampled population is representative of the target population.

- 3) Do you have any suggestions for more effective graphic presentation of the data?
If yes, please describe.

Goldman: No.

Listorti: It would be useful to give a graphic similar to Fig. 219-1 “Percent of the 1,714 High Priority ...” which shows potential risk of other sites besides those on the NPL list.

Ryan: *The presentation is quite clear with both trends and partitioning well presented.*

Walker: [no answer provided]

- 4) Please provide any additional comments, suggestions, or concerns regarding the indicator that you have not already noted in Questions 1 through 3. In particular, note any limitations to the indicator that you have not already described in your responses to the preceding questions.

Goldman: See above; I need more information to understand what is meant by “exposure” and “under control” and how this is assured over time.

Listorti: [no answer provided]

Ryan: *None.*

Walker: [no answer provided]

- 5) Overall, this indicator:

Goldman: X Should be included in ROE06 TD.

Listorti: X Should be included in ROE06 TD.

Ryan: X Should be included in ROE06 TD.

Walker: X Should *not* be included in ROE06 TD.